EXHIBIT "A"

Deposition Transcript of Anatoly Aleksandrovich (May 18, 2018)

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

- - -

GARY BRYAN BRACKIN, Individually and in his capacity as Surviving Spouse of PAMELA W. BRACKIN, deceased, Plaintiff,	:	CIVIL ACTION
v.	:	NO. 2:17-cv-2101
MEDTRONIC, INC., et al., Defendants.	:	

STATE OF MINNESOTA
COUNTY OF HENNEPIN - FOURTH JUDICIAL DISTRICT

CHARLES EKLUND, Plaintiff,	:	
v.	:	
MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC MINIMED, a Division of MEDTRONIC, INC.; UNOMEDICAL DEVICES S.A. de C.V., and UNOMEDICAL A/S, Defendants.	:	NO. 27-CV-17-18038

- - -

May 18, 2018

DEPOSITION OF ANATOLY ALEKSANDROVICH

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Videotaped teleconferenced deposition of ANATOLY ALEKSANDROVICH taken pursuant to notice, was held at 16501 Ventura Boulevard Suite 400 Encino, California, beginning at 9:46 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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GOLKOW LITIGATION SERVICES
877.370.3377 ph| 917.591.5672
deps@golkow.com

APPEARANCES:

WILLIAMS CEDAR LLC
BY: KEVIN HAVERTY, ESQUIRE
1515 Market Street
Suite 1300
Philadelphia, Pennsylvania 19103
(215) 557-0099
khaverty@williamscedar.com
Representing the Brackin Plaintiffs

GARY K. SMITH LAW FIRM, PLLC
BY: PHILIP M. CAMPBELL, ESQUIRE
The Forum III
1770 Kirby Parkway, Suite 427
Memphis, Tennessee 38138
(901) 308-6484
pcampbell@garyksmithlaw.com
Representing the Brackin Plaintiffs

GOLDENBERG LAW, PLLC
BY: MARLENE GOLDENBERG, ESQUIRE
800 Lasalle Avenue
Suite 2150
Minneapolis, Minnesota 55402
(855) 975-6581
mjgoldenberg@goldenberglaw.com
Representing the Eklund Plaintiffs

GREENBERG TRAURIG, LLP
BY: CLIFF MERRELL, ESQUIRE
3333 Piedmont Road, NE
Suite 2500
Atlanta, Georgia 30305
(678) 553-2100
merrellc@gtlaw.com
Representing Medtronic

APPEARANCES (cont.'d):

MASLON LLP
BY: NICOLE E. NAROTZKY, ESQUIRE
3300 Wells Fargo Center
90 South Seventh Street
Minneapolis, Minnesota 55402
(612) 672-8200
nicole.narotzky@maslon.com
Representing Medtronic

THOMPSON HINE LLP
BY: Z. ILEANA MARTINEZ, ESQUIRE
Two Alliance Center
3560 Lenox Road NE, Suite 1600
Atlanta, Georgia 30326
(404) 541-2900
ileana.martinez@thompsonhine.com
Representing Unomedical A/S in the Eklund Litigation

VIDEOGRAPHER:
DAVID KIM

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MS. MARTINEZ: I just wanted to say, this is Ileana Martinez from Thompson Hine, that I am appearing on behalf of Unomedical A/S in the Eklund case only and only for defendant Unomedical A/S, which is the only defendant that has been serve in the Eklund case. And based on the motions and the court's order in the Brackin case from yesterday, I will not be appearing and am not appearing on behalf of any defendant in the Brackin case, because we, based on the motions to dismiss and motion to quash and motion for protective order, our position is that we have not been -- Unomedical A/S and Unomedical Devices has not been served at all, and Unomedical A/S has not been properly and timely served.

That's all. Thanks.

MS. GOLDENBERG: All right. I will go next.

This is Marlene Goldenberg, and I am here on behalf of the Eklund family.

I just wanted to note for the record that while I don't believe that there is going to be an issue, I would like to leave the deposition open today, subject to the production of any documents that I don't have yet in the Eklund case.

MS. NAROTZKY: And this is Nicole Narotzky on behalf of Medtronic. And a couple of things, just in response, Marlene, to your statement.

You know, we would be willing certainly to meet and confer on that in the future if need be but don't believe that will be necessary, given the productions that have been made and agreed to.

The other thing that I would like to add is that, you know, we have been discussing the cross-notice stipulation between the plaintiffs and defendants, Medtronic defendants in the Eklund and Brackin cases. And while we have agreement on that from this morning that has not yet been filed with the court, I

would just note that the deposition is being taken pursuant to the agreement that we reached in that stipulation.

Any objections or comments on that?

MR. HAVERTY: No.

MS. MARTINEZ: No. That's fine.

MR. HAVERTY: No. We agree.

MR. MERRELL: And then I have one last thing, just so we don't have to break up the flow. The deposition today is being taken pursuant to the protective orders entered in the Eklund and Brackin cases.

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(A discussion off the record occurred.)

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THE VIDEOGRAPHER: We are now on the record. My name is David Kim. I'm a videographer for Golkow Litigation Services. Today's date is May 18, 2018, and the time in Encino is 9:48 a.m. This video deposition is taking place in

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Encino, California, in the matter of Brackin v. Medtronic, Inc., et al., and is cross-noticed with other cases.

This is for the US District Court, the Western District of Tennessee. The deponent is Anatoly Aleksandrovich. Counsel will be noted on the stenographic record.

The court reporter is Ann Marie Mitchell and is in Philadelphia, and she will now swear in the witness.

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ANATOLY ALEKSANDROVICH, after having been duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. HAVERTY:

Q. Good morning, Mr. Aleksandrovich. It's nice to see you again.

A. Good morning. Likewise.

Q. I'm sure you remember well about three years ago when we were together for those

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grueling depositions. Hopefully I'm not going to try to re-plow any of that ground too much, but I want to take your deposition today concerning some developments that have happened as well since that time, back in 2015 when we last met.

Before we begin, let me give you some instructions so that hopefully you understand me, I'll understand you, and we'll get through this process as quickly as we can.

The first is that if at any time I ask you a question that you don't understand or it doesn't make sense to you, please tell me that and I'll try to rephrase the question or otherwise make it understandable. All right?

A. Okay.

Q. When you do give me an answer, please make it a yes or a no or a narrative, descriptive answer, because there is a court reporter here taking down the testimony, and she can't take down gestures like nods of the head and shrugs of the shoulders. And even though you may say uh-huh or uh-uh in response to a question and we know sitting here today that you mean yes or no, later on when this comes out in transcript

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form, we may not whether the answer is yes or no. So for the purposes of clarity and accuracy, please give a yes, no or a narrative, descriptive answer. All right?

A. Understood.

Q. Closely related to that is please wait for me to finish asking my question before you try to answer it. There are two important reasons for that. One is that the court reporter can't take down gestures like nods -- or excuse me, can't take down both of us speaking at the same time, but also that way you can understand -- you can assure yourself that you understood my question before you try to give an answer. Okay?

A. Okay.

Q. And one other factor is playing into this, is there's a little bit of a lag on the audio, so hopefully that won't be too much of an issue, but...

Also, if at any time I ask you a question that you don't have an exact answer to or -- but you can provide us with a reasonable approximation or estimation as distinct from a

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guess, it's okay to do that. Just please tell us that you're approximating or estimating, so that we understand whatever limitations or qualifications there may be on your answer. All right?

A. Okay.

Q. Very good.

Let me just go back a little bit with some of your background.

What's your education and training?

A. Master's degree in manufacturing engineering.

Q. Where did you get that degree?

A. In Tashkent State Technical University.

Q. In the former Soviet Union?

A. Correct.

Q. And where did you get your undergraduate degree?

A. Same -- there is no -- there is no distinction. It was one program that graduated with the master's.

Q. Okay. They don't do it in the

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way we do it in the US where it's undergraduate and then you go to graduate school?
A. That is correct.
Q. Okay. Great. By the way, let me go back to something else before we get into your background and your education and training.
You've obviously given prior deposition testimony on behalf of Medtronic. Correct?
A. I have.
Q. Other than the deposition that you gave in the Dennert and Kubicki matters back in 2015, how many other depositions have you given on behalf of Medtronic?
A. One or two. I don't remember exactly.
Q. Do you recall when the last time you gave deposition testimony was?
A. No, I don't recall.
Q. Okay. Do you know whether it was within the last three years?
A. It was before you took my deposition last time.
Q. Okay. So the deposition that I

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took of you in 2015 was the last time that you testified on behalf of Medtronic?
A. That is correct.
Q. All right. Are you scheduled to give any deposition testimony on behalf of Medtronic other than this case or these cases at this point?
A. No, not at this point. No.
Q. And I don't really remember from your prior deposition, but the deposition testimony that you gave prior to the 2015 depositions, did that have anything to do with your role in running the CAPA involved with the temporary vent block phenomenon?
A. I don't remember exactly what the previous deposition was on.
Q. Okay. Did you give any deposition testimony concerning the Lot 8 recall?
A. No.
Q. Were you involved at all in the Lot 8 recall or the CAPA, anything like that?
A. No, I was not.
Q. So you told us that you have a master's degree in manufacturing engineering.

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When did you get that degree?
A. In 1993.
Q. And did you come to the US right after that, or did you work in -- I guess by 1993 it was then -- the Soviet Union had broken up. Right?
A. It was about to break up, yes.
Q. So did you remain in Russia or whatever it was that you were in, or did you come to the US?
A. No. I came to the US in September of 1993.
Q. And how did you come to the US? What was the arrangement for that? How did you get a job?
A. By -- by how, do you mean how did I arrive physically or my alien status?
Q. I'm talking about why did you come to the US? Did you have a job here at that point?
A. No. The family decided to immigrate.
Q. Okay. So when you came in September of 1993, did you -- were you able to

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get a job at that point?
A. Soon after that.
Q. And what did you do?
A. Started as an inspector at a small manufacturing company in Los Angeles.
Q. What was -- what did they manufacture?
A. It was a job shop that specializes in powder and metallurgy technology.
Q. By the way, within the practice of manufacturing engineering, did you have any particular specialization?
A. Yes. From an educational standpoint, it was -- it was concentrated around metal cutting technology.
Q. Metal, I'm sorry, metal what?
COURT REPORTER: Cutting.
THE WITNESS: Metal cutting.
BY MR. HAVERTY:
Q. Is quality assurance part of manufacturing engineering?
A. It was not by my training.
Q. Is it in your practice, though?
A. In my practice, yes. Quality

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assurance is a part of anything and everything.
Q. So you were working at this metal company.
Then what did you do after that?
A. Then after that, I went to a company that manufactures turbo generators.
Q. Okay. And what did you do there?
A. A variety of things, progressing from quality inspector to test engineer to manufacturing engineer to project manager.
Q. For how long were you with that firm?
A. Seven years, I believe.
Q. So this takes us into the early 2000s?
A. I was laid off from that company in the late 2002.
Q. Okay. And what did you do after that?
A. I went to another small company that made -- worked on the power storage technology.
Q. Okay. And what did you do there?
A. Manufacturing engineering.

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Q. And what did -- what did the role of manufacturing engineer involve at that company?
A. At that company was to set up a manufacturing line for this product that the company was working on and equip it with proper equipment and also establish relationships with a supplier for a long-term manufacturing plant.
Q. And for how long did you have that job?
A. Just one year.
Q. And what did you do after that?
A. Then I went to the aerospace company.
Q. Okay. And what did you do there?
A. I was there trained as a Six Sigma Black Belt and primarily worked in the manufacturing field as well.
Q. And for how long did you have that job?
A. Let's see. 2003 -- three years.
Q. And that takes us up to 2006?
A. Correct.
Q. And what did you do after that?

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A. After that I went to my first medical device company --
Q. What -- what --
A. -- as an industrial engineer.
Q. And what company was that?
A. Advanced Bionics.
Q. Event Bionics?
A. Advanced Bionics.
Q. Advanced Bionics. Okay.
And you said you were a industrial engineer. How did that differ from a manufacturing engineer?
A. By -- in that particular assignment, mostly by name. Instead of concentrating on necessarily manufacturing processes, my job was to -- to set up the facility and auxiliary processes to ensure that manufacturing happens in the most efficient way.
Q. It was more of an umbrella type of an assignment rather than a more specific setting up manufacturing processes?
A. That is correct, yes.
Q. And for how long did you have that job?

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A. Until 20 -- late 2008.
Q. And what did you do then?
A. Then Medtronic.
Q. Okay.
A. Starting in January 2009.
Q. And how did you get the job at Medtronic in January of 2009?
A. I applied to an open position, posted, I believe, on their website.
Q. What was the position?
A. I don't remember exactly. It was a senior engineer. I don't remember exactly what kind of engineer.
Q. Okay. And what were your -- what were your job duties at that time? What lines were you involved in?
A. I'm sorry. I didn't catch your -- the last part of the question.
Q. Yeah.
A. What lines I was involved with?
Q. What products were you involved with when you came to Medtronic?
A. Oh. It was a glucose sensor manufacturing line.

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Q. And what was your job?
A. Like I said, senior engineer and working on the manufacturing line, ramping up production, setting up.
Q. That was a bad question.
What I meant was, could you give me some sort of sense of what your job duties were?
A. Okay. Validating processes, procuring new equipment, installing it, validating it and bringing it to production state, working on setting up manufacturing lines for newly-introduced products, working with suppliers to ensure an uninterrupted flow of parts.
Q. And let me just explore something a little bit.
You talked about part of your job is validating processes.
Do I understand that to mean that basically when you're preparing a manufacturing type of a system, you want to understand the processes that go into that are -- actually work to do what they're supposed to do, and that's

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what you call validating them?
A. That's part of it.
Q. Okay.
A. It's a little more than that. It's understanding the process and then identifying the process and ensuring that the process produces what's needed reliably and repeatedly.
Q. Now, that type of validation practice, is that a specialization within the practice of manufacturing engineering?
A. No. I would not call it that, no. Because manufacturing engineering covers much more than just medical devices, and validation is specific to medical devices.
Q. Oh, okay. So in other types of manufacturing processes, you don't necessarily have that type of a validation process?
A. That is correct. Either no validation at all, it's done through a different way, or not to the extent that it's done in the medical device industry, so the answer is yes.
Q. Okay. And just so I understand, this validation process in the medical device

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industry that you're talking about is something that's part of the FDA requirements for medical devices, is it not?
A. It is.
Q. And that's under the Quality Systems Regulations. Correct?
A. Correct.
Q. That's Part 820 of the federal rules?
A. I don't remember the number of the regulation.
Q. Okay. But in any event, there's a specific regulation that deals with, among other things, validation of processes. Correct?
A. As far as I understand, yes.
Q. And we're going to get into this in a little bit more detail in a bit, but also part those regulations is a process of corrective and preventative actions too. Correct?
A. I am not sure if this is the same regulation as the validation.
Q. No. I'm not suggesting it is, but I'm saying that within the quality systems regulations, another thing in addition to

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validation processes is a requirement to have in place corrective and preventative action procedures. Correct?
A. That is correct.
Q. And those are FDA requirements. Right?
A. Yes.
Q. Okay. So when you were -- when you first joined Medtronic in 2009 and you were working on the glucose monitor system, how long did you do that position?
A. For about three years.
Q. And then what did you do?
A. And then I switched to consumables.
Q. And what did the consumables consist of?
A. Mostly infusion sets and accessories to those infusion sets.
Q. Did it also include the reservoirs?
A. Consumable -- consumables do include reservoirs. I am not involved with reservoirs.

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Q. Were you ever involved with reservoirs?
A. Not to any serious extent.
Q. Okay. So what was your job when you moved to consumables relating to the infusion sets?
A. Basically oversee the manufacturing relationship with the supplier that makes infusion sets. We don't make them ourselves. And the entire manufacturing site of the infusion set production, if you will.
Q. And in 20 -- well, that was about 2012 that you moved over to consumables?
A. Yes, that is correct.
Q. Okay. And at the time when you moved to consumables in 2012, who was the manufacturer of the infusion sets?
A. Unomedical.
Q. And did you, as part of your job, did you develop a relationship with Unomedical about the manufacture of the infusion sets?
A. So the -- the company-to-company relationship were well established by then. I developed my personal relationship with

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Unomedical.
Q. And what kinds of things -- were there certain projects that you were working on when you moved over to consumables?
A. Yes. There is different ones.
Q. Can you give me just some sampling of some idea of some of the projects that you were working on relating to the infusion sets?
A. It can be anything. It can be a material change. It can be an equipment setup or equipment expansion. It can be capacity increase project. It can be packaging project or branding project. All kind of things.
Q. In 2012 when you first got involved with the consumables, what kinds of projects like you just described did you have going at that time, if any?
A. Probably all of the above, to some extent, more -- more some than others.
Q. The manufacture of the infusion sets also included the manufacture of the proprietary connector cap. Correct?
A. That is correct.

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Q. And that was something that Unomedical also manufactured and then assembled with the infusion sets to -- or with the catheters to create a complete infusion set. Correct?
A. That is correct.
Q. And do you know for how long that system had been in place, that Unomedical manufactured both the cap, the connector cap, and assembled the completed infusion set?
A. No, I don't exactly.
Q. Did you know that it had been fairly long-standing at that point?
MS. MARTINEZ: Object to the form.
THE WITNESS: Yes.
BY MR. HAVERTY:
Q. And when you first came over in 2012 to consumables, do you know whether there were any material changes that were in place or in progress at that time?
A. No. To the best of my knowledge, there was no such project at that time.
Q. Was there -- were there any

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changes in the manufacturing processes that were contemplated or in progress at that time?
A. No, not that I can remember.
Q. So what would your day-to-day job be in dealing with the consumables that were manufactured by Unomedical?
A. Mostly documentation change, updates, review of validation documents provided by Unomedical, things like that.
Q. Okay. And what types of validation documents was Unomedical providing to you relating to the manufacture of the infusion sets?
A. Unomedical usually supplies a summary report of validation activities.
Q. And what do those validation activities involve?
A. They involve establishing the manufacturing process and verification that the process performs consistently within set parameters.
Q. And were they providing you these summary reports on validation activities on a regular basis?

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MS. MARTINEZ: Object to the form.
THE WITNESS: It depends on the -- on the project.
BY MR. HAVERTY:
Q. So there wasn't anything in place that said on a monthly basis you will provide us validation summaries?
A. That is correct. There is no such schedule.
Q. So what would trigger a validation report from Unomedical? Would it be some change in the manufacturing process or some -- some defect or something that was discovered in the manufacturing process?
MS. MARTINEZ: Object to the form.
THE WITNESS: A change in the manufacturing process, an introduction of a new piece of equipment, a move of a piece of equipment from one place or another, things like that.
BY MR. HAVERTY:
Q. And are you still in that same

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position today that you were when you first joined in 2012?
A. Yes.
Q. Okay. And what's your title now?
A. Senior principal manufacturing engineer.
Q. And do you still have responsibility primarily for the infusion set consumables?
A. Primarily, yes.
Q. Do you have responsibility for any other products associated with the insulin infusion pumps?
A. With the pumps, nothing other than the belt clip.
Q. Oh, the belt clip. Okay.
Is the belt clip manufactured by Medtronic too?
A. No, it is not.
Q. Okay. Who manufactures that?
THE WITNESS: Can I disclose it here?
MR. MERRELL: Yes.
THE WITNESS: It is manufactured

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by a company -- it is manufactured by a company called SMC.
BY MR. HAVERTY:
Q. Are there any other products that you oversee other than the belt clip and the infusion sets?
A. Some accessories to the infusion set, inserting mechanism, inserting devices. And there is also a couple of new products that I got involved with that -- that are not part of the consumables product line, if you will.
Q. Let me go back a little bit, talk to you about the connector cap for the infusion sets.
The purpose of that connector cap is to connect the catheter which delivers the insulin into the body to the reservoir which holds the insulin. Correct?
A. Correct. And to the pump.
Q. Right. Well, right. Because then you connect it to the reservoir, the reservoir goes in the pump, and the pump pumps the insulin through the reservoir into the catheter, into the body. Correct?

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A. Correct.
Q. And you are aware that that connector cap is a proprietary, patented design of Medtronic. Correct?
A. Correct.
Q. And were you aware that there was a period of time when Medtronic actually did manufacture that connector cap?
A. I am aware of that, yes.
Q. And how did you become aware of that?
A. By learning the history of a proprietary cap manufacturing.
Q. And was it your understanding that part of the reason for the design of that connector cap is because Medtronic was seeking to make the pump waterproof?
A. No. That's not the main reason for the proprietary cap.
Q. Okay. What is your understanding of what the main reason for the proprietary cap was?
A. Main reason is that Medtronic pump connects only to Medtronic-designed infusion

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set.
Q. So is it your understanding that no other types of infusion sets could be used with a Medtronic pump?
A. Other than infusion sets equipped with a proprietary connector, yes.
Q. So -- and so the reservoirs are designed specifically for that connector cap as well?
A. Correct.
Q. Can those reservoirs be used with a standard Luer Lock connector?
A. So we're going to have to be a little bit more clear on this.
We do or we used to manufacture a reservoir that will work with the Luer Lock connector. And then there are reservoirs designed and manufactured to work only with a proprietary connector.
Q. So the reservoirs that are designed for connection with the proprietary connector will not work with a Luer Lock connector?
A. That is correct.

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Q. Are there reservoirs out there that are not Medtronic reservoirs that would still work in a Medtronic pump?
A. No, not to my knowledge.
Q. So again, are the reservoirs that are designed to connect only to the proprietary cap, are they the only reservoirs that will work in a Medtronic 5 series pump?
A. Yes. To the best of my knowledge, yes.
Q. And we're going to get into this in a little bit more detail shortly, but you led the corrective and preventative action -- and we're going to call them CAPAs from now on for the benefit of the court reporter -- involve -- dealing with the temporary vent block phenomenon. Correct?
A. Correct.
Q. Other than that CAPA, have you ever been involved with any other CAPAs at Medtronic?
A. I don't remember. Definitely not as a lead. As a team member I may have, but I don't remember.

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Q. You don't remember any CAPAs that you might have been involved in other than the CAPA involving the temporary vent block. Right?
A. Correct.
Q. And you were aware, though, when you came on to the consumables about the Lot 8 recall. Correct?
A. That is correct.
Q. And were you aware of the Lot 8 recall when it first happened? You were working at Medtronic at that time in 2009. Right?
A. Yes.
Q. Okay.
A. But I was not aware right as it happened, because I was not involved with that product line at the point -- at the time.
Q. Okay. Because you were doing the glucose monitors. Right?
A. That's correct, yes.
Q. But at some point you became familiar with the details of the Lot 8 recall?
A. Yes.
Q. Was that before or after you headed up the CAPA relating to the vent block?

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A. Before.
Q. And do you recall how you became aware of the details of the Lot 8 recall?
A. Yeah. By a company-wide announcement.
Q. And what was your understanding of what the problem was that led to the Lot 8 recall?
A. It was a manufacturing process issue.
Q. And what did that manufacturing process issue do that caused the recall, that led to the recall?
A. So the manufacturing process employed at that time included deposition of some silicone oil onto the inner surface of the P-cap to prevent -- to -- to make the connection easier and to prevent the sounds the two materials were make -- were to make. And that eventually led to some of that silicone oil being deposited onto the membrane and rendering it gas impermeable.
Q. So that -- and just -- we're going to talk about this in more detail. But that's exactly the same failure mechanism as was

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discovered in the temporary vent block phenomenon. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: No, not the mechanism. Failure mode. The failure itself but not the mechanism.
BY MR. HAVERTY:
Q. I stand corrected. Yes. You're right.
The failure mode was the same, and that is blocking of the vents that prevents equalization of the pressure. Right?
A. Potentially, yes.
Q. Okay. So back at the time of the Lot 8 recall, Medtronic was aware of a problem with insulin delivery if the vents in the proprietary cap got blocked. Right?
MR. MERRELL: Objection to form.
THE WITNESS: Yes. After investigation of Lot 8, yes.
BY MR. HAVERTY:
Q. Let me shift gears a little bit and talk about CAPAs. We were touching on this a little bit.

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CAPAs stand for corrective and preventative actions. Correct?
A. Correct.
Q. And would you agree with me that a CAPA is a high-level risk mitigation process?
A. It's not just the risk mitigation process, but in general, yes.
Q. It's not something that you enter into just because you find some type of a small deviation from something. It's usually where there's a hazard that's been identified, and that hazard poses a risk to patients' health and safety. Right?
MR. MERRELL: Objection to form.
MS. MARTINEZ: Same objection.
THE WITNESS: There is a -- there is a multistep process -- we didn't call it a system -- at Medtronic that leads to a CAPA. And not every failure identified or not every deviation identified results in a CAPA. There are many different ways to address an issue identified.
BY MR. HAVERTY:
Q. Right. And that's what I want to

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talk about a little bit.
What is it that would trigger a CAPA ultimately?
A. I can't answer that question directly. First of all, I'm not in the quality systems -- I mean, I'm trained on all the quality systems, but there are multiple steps leading to a CAPA, and I cannot tell you just one way or the other what exactly leads to a CAPA. It's a complex of -- of activities involving a lot of people from different functions.
Q. But again, that's kind of a -- there's a multistep process that leads to a decision about whether to open a CAPA or not open a CAPA. Correct?
A. Correct.
Q. And part of that decision-making is an assessment of the risk to patient safety. Correct?
A. That is correct.
Q. And again, when we talk about it's a corrective and preventative action, the corrective part of it means that you -- you're correcting a problem in the near term. Correct?

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A. Not necessarily correct. You can correct it in the near term or in the long term. It depends on the corrective action --
Q. Right.
A. -- identified.
Q. Right. What I'm saying is, is that initially you want to correct whatever the perceived problem is and understand what the root cause is and then take preventative action to prevent that problem from arising in the future. Right?
MR. MERRELL: Object to the form.
THE WITNESS: That's -- that's high level. But again, it's very, very specific to an issue at hand.
BY MR. HAVERTY:
Q. Right. I'm just trying to understand the concept of the process. The process -- that's why it's called corrective and preventative. So first things first is you correct the perceived problem, and then you figure out whether there's anything necessary to be done to prevent that problem from arising again in the future. Right?

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MR. MERRELL: Object to the form.
THE WITNESS: Correct.
BY MR. HAVERTY:
Q. So the corrective action might be something like a field notification or a recall. Right?
A. Depending on the situation, might be.
Q. Right. And a preventative action might be perhaps a redesign of the product to mitigate or eliminate whatever hazard is perceived. Correct?
A. Might be. Again, depending on the situation. Correct.
Q. Okay. And again, we talked about this a little while ago. This is something that is required by the FDA to be in place. Correct?
A. Yes, it is.
Q. So -- and are you required to report to the FDA when CAPAs are opened and what the dispositions of those CAPAs are?
A. I wouldn't be able to -- I don't know exactly how reporting happens and what drives reporting.

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Q. Okay. And let's talk a little bit about -- we touched on it a little bit, but risk mitigation as CAPA is one part of that process.
You would agree with me that there is a hierarchy of risk mitigation -- risk mitigation processes, the first being if you detect a hazard, you try to design that hazard out. Right?
MR. MERRELL: Object to form.
THE WITNESS: I'm not very clear on the question.
BY MR. HAVERTY:
Q. Okay. It was a terrible question, and I apologize.
You're aware that there's a hierarchy of risk management techniques?
A. Correct.
Q. Or risk mitigation techniques. Correct?
A. Yes.
Q. And the hierarchy -- the hierarchy, the most desirable technique for risk mitigation is to design out a hazard. Correct?

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A. Correct.
Q. And then the next most preferable is if you can't design the hazard out, then you guard against it. Correct?
A. Correct.
Q. And both of those risk mitigation techniques are designed to take out the human factor in risk mitigation. Correct?
A. As much as possible.
Q. And then the third risk mitigation technique and the least desirable of the three is if you can't design the hazard out and you can't guard against it, then you warn about it. Right?
MR. MERRELL: Object to form.
THE WITNESS: Yes.
BY MR. HAVERTY:
Q. And the problem with warnings is that it still involves the human factor. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: Yes.
BY MR. HAVERTY:
Q. And when you open up these CAPAs

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where you've identified a particular hazard or some issue, is that part of the CAPA process is to go down the list of the hierarchy to determine whether or not you can design the problem out, whether you can guard against it or whether you're left with having to warn about it?
A. So the process you're referring to is not a part of my responsibility at Medtronic, and I'm usually not involved in that early stage of the CAPA, so I can't really answer exactly how it happens and how it's supposed to happen.
Q. Right. But part of the CAPA process is, well, we'll just do it, is the first thing you want to do is you identify the root cause of the problem. Correct?
A. Once you go into investigation phase of the CAPA, yes.
Q. Okay. And let's go back and talk specifically about the CAPA that was opened relating to the vent block in 2013.
That CAPA arose out of complaints, and then there was a situation analysis done and a health hazard evaluation was

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done and a risk assessment. Correct?
A. Correct.
Q. And based upon those initial stages of the investigation, there was a determination that was made to open up a CAPA. Correct?
A. Correct.
Q. And you would agree with me -- I'm going to shift gears a little bit -- but that in the spring of 2013, Medtronic uncovered a hazard that was associated with the design of the proprietary connector cap. Correct?
MR. MERRELL: Objection to form.
MS. MARTINEZ: Objection.
THE WITNESS: No, no. Incorrect.
BY MR. HAVERTY:
Q. What was incorrect about that? Did Medtronic identify a hazard?
A. The hazard was identified, that is correct, but it was not connected or due to design issues.
Q. Well, it was due to a material in the underside of the connector cap that could become gas impermeable if it got wet. Correct?

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MR. MERRELL: Objection to form.
THE WITNESS: That is correct.
BY MR. HAVERTY:
Q. And that was -- that was the original design of the -- that membrane material in the P-cap, that it would -- it was a two-layer membrane. Correct?
A. It was the original design, but the unit was not designed or not intended to be used in the environment where any type of liquid would be present on that surface.
Q. Right. But the fact is, is that you identified a hazard that was associated with the design. The design of that connect -- the membrane material in that P-cap could give rise to a hazard if it got wet on the inside. Correct?
A. Correct.
MR. MERRELL: Objection to form.
THE WITNESS: As a consequence to not following instructions.
BY MR. HAVERTY:
Q. Right. But the fact is, is that there was a design flaw in it that, you know, it

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was finally uncovered in 2013. Right?
MR. MERRELL: Objection to form.
THE WITNESS: Again, I wouldn't call it a design flaw, but yes, it was an issue.
BY MR. HAVERTY:
Q. Okay. And in fact, when a determination was made to redesign that material to mitigate the hazard. Correct?
A. Ultimately, yes.
Q. Okay. So the initial thought process was we've identified a hazard, and were you tasked with the job of determining whether or not in the hierarchy of risk mitigation, that hazard could be designed out?
A. I was tasked eventually with -- yes. With -- to lead the team to figure that out.
Q. Okay. And that's because that was Medtronic's preferred method of risk mitigation?
MR. MERRELL: Objection to form.
THE WITNESS: There is no preferred method to risk mitigation. It

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can consist of a number of different things.
BY MR. HAVERTY:
Q. Well, again, we were talking a little bit earlier about it is if you identify a hazard, the most preferable course of action is to see if you can design that hazard out. Right?
A. True. But that's not Medtronic specific.
Q. Right. But am I correct that Medtronic made a commitment to the FDA that they would look to see if they could design alternative membrane material to mitigate that hazard?
A. Okay. I can't speak to the commitments made to the FDA, and I'm not very familiar with that correspondence between Medtronic and FDA; but the project team determined that that -- to redesign or to introduce a new material would be the ultimate solution to the problem.
MR. HAVERTY: Cliff, do you want to take a real -- like a two-minute break right here, because --

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THE WITNESS: That would actually be nice.
MR. HAVERTY: Would that be perfect?
MR. MERRELL: Sure.
MR. HAVERTY: Okay.
MR. MERRELL: Yeah, that's fine.
THE VIDEOGRAPHER: We are now going --
MR. HAVERTY: I'm sorry. Go ahead.
THE VIDEOGRAPHER: We are now going off the record, and the time is 10:29 a.m.
- - -
(A recess was taken from 10:29 a.m. to 10:39 a.m.)
- - -
THE VIDEOGRAPHER: We are now going back on the record, and the time is 10:39 a.m.
BY MR. HAVERTY:
Q. Mr. Aleksandrovich, the hazard that we were talking about involving the

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temporary vent block, that was first uncovered arising out of a complaint from a customer in September of 2012 about an anomaly during the priming process of the pump. Correct?
A. To the best of my knowledge, yeah. I joined the project team much later than that.
Q. Right. But your understanding was that that's what -- that's what set everything in motion initially. Correct?
A. Yes.
Q. And your understanding is that they provided a video of this phenomenon as well. Correct?
A. There was a video, yes, correct.
Q. And you've seen that video. Correct?
A. Correct.
Q. This is -- I believe it's Exhibit 6, but let me check here real quickly.
I just want to play that video. I believe it's Exhibit 6. There's a -- there's a placeholder -- yeah. It's Exhibit 6.
In the binder there, Cliff. It's

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a placeholder for the pumpenfehler video.
MR. MERRELL: Do you want us to have it out or anything or -- or just give it to --
MR. HAVERTY: No. I just want to let you know that --
MR. MERRELL: Okay.
MR. HAVERTY: Just so you can identify it.
MR. MERRELL: Understood.
MR. HAVERTY: This is Exhibit 6 -- not this one. No, the other one.
- - -
(Deposition Exhibit No. AA-6, Video file, was marked for identification.)
- - -
MR. HAVERTY: So anyway, Cliff, that is just a placeholder for the video, Exhibit 6.
MR. MERRELL: Understood.
MR. HAVERTY: All right. So we're going to play this.
BY MR. HAVERTY:

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Q. Okay. Can you see that? Can you see the video there of the pump?
A. Yes.
Q. Okay. Great. We're going to play it. So if you can take a look at this, Mr. Aleksandrovich.
- - -
(Video played.)
- - -
BY MR. HAVERTY:
Q. Mr. Aleksandrovich, you recognize that video as the video from Germany that was -- started this whole process, the investigation?
A. I do.
Q. Okay. And you've seen that before. Correct?
A. Correct.
Q. And I probably will need to play it for you again, but I just want to ask you a couple of questions.
Would you agree with me that what was seen on that video is that the stopper in the reservoir began moving before the slide screw engaged the reservoir stopper?

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A. That is correct.
Q. And would you also agree with me that the slide screw seated itself even while the reservoir was moving -- reservoir stopper was moving on its own?
A. I don't think I've seen the seating mechanism. I think the priming action was stopped before it seated itself.
Q. Okay. Let's go back and play that then again. Let's see.
A. Okay.
- - -
(Video played.)
- - -
BY MR. HAVERTY:
Q. So you can see that it's advancing there. Correct?
A. Yes, correct.
Q. And right about there the reservoir stopper starts to move.
A. Right?
Q. Do you see it?
And then you hear the three beeps.

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Isn't that the seated -- the slide screw has seated at that point. Correct?
A. I'm not familiar with the -- with the audible signals that the pump makes when it's seated, but it's clearly not seated.
Q. Well, no. My question is a little bit different.
My question is, is that the slide screw advances until it detects a certain pressure, and then it detects itself as having been seated. Correct?
A. Again, I'm not -- I'm not -- to my shame, actually, I'm not that familiar with the pump operate -- operating, but visually right now what I'm seeing in the picture on the screen, the slide is not engaged with the plunger.
Q. Right. But that's different than specifically what seating is. Right?
A. No, I don't think so. Seating means that they're connected to the point where therapy can start.
Q. Right. But that's -- let me ask this question: You see that the person's finger is still on the "act" button. Correct?

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A. Yes, but it doesn't mean that they stop pushing it.
Q. Well, that's what I'm saying, is that the person's finger is still on the "act" button, but the slide screw has stopped on its own. Correct?
Do you want to play it again?
A. Yes. Because I don't agree with what you're saying.
MR. HAVERTY: Back up a little bit.
THE WITNESS: Just a couple of seconds, not the whole thing.
- - -
(Video playing.)
- - -
BY MR. HAVERTY:
Q. Yeah. And you'll hear the three audio beeps, and you'll see that the finger is still on it, and yet the slide screw stops. Right?
A. Yep, okay.
Q. So is it your testimony that you do not believe that the slide screw there has

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detected that it was seated?
A. Again, I can't answer that question. I'm not that familiar with the pump operation.
- - -
(A discussion off the record occurred.)
- - -
BY MR. HAVERTY:
Q. Now, you would agree with me that there was also -- in addition to this video, there were also reports from -- also from Germany, and they had returned infusion sets for examination. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: I don't remember details to that extent.
BY MR. HAVERTY:
Q. Okay.
A. Again, I joined the team later than -- later -- at a later date.
Q. Right. Okay. So if you could look at Exhibit 2.
- - -

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(Deposition Exhibit No. AA-2, CAPA Full Detail Report with five Family Tree Levels - PDF, Bates stamped MDT-BRACP-028983 through MDT-BRACP-029065, was marked for identification.)

- - -

MR. MERRELL: We have a slight binder malfunction. Sorry. It's bent now.

MR. HAVERTY: I put a lot of care into that, Cliff.

MR. MERRELL: I'm sure you did, but unfortunately UPS may not have put the same care into it. Oh, it's a serious malfunction.

It's okay. Let's pull it out. We'll just have to pull it out.

That's -- which maybe is easier anyway.

BY MR. HAVERTY:

Q. And let me just ask you a couple of -- are you okay? -- foundational questions, Mr. Aleksandrovich. This Exhibit 2 is captioned as a "CAPA Full Detail Report with five Family

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Tree Levels."

Do you see that?

A. Yes.

Q. Okay. And underneath that, it has a -- well, the PR number is 158416. That's the CAPA ID number?

A. Correct, yes.

Q. Okay. And this was created on April 30th of 2013. Correct?

A. Looks like it, yes.

Q. And this was the CAPA that you -- you led. Correct?

A. Yes, it is.

Q. And it's titled "QIR#13-006 P-cap Infusion Sets Prime Fill Anomaly." Correct?

A. Correct.

Q. And what this report that you're looking at is -- as Exhibit 2 is actually the CAPA closing document, is it not?

A. It's the entire report on the CAPA, not necessarily closing. This is the last version of that report, yes.

Q. Right. Which means that the CAPA was closed at that point. Correct?

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A. Correct.

Q. And indeed, it says up there at the top, "PR State: Closed - Done." And underneath it says, "Since: 10-November-2016." Correct?

A. Yes, correct.

Q. So that's when this CAPA was closed out. Correct?

A. Correct.

Q. So it was opened for about three-and-a-half years. Right?

A. Yes.

Q. Okay. And if you look down under the "Description" -- and I assume this CAPA document went through multiple iterations over the course of three-and-a-half years. Correct?

A. Correct.

Q. But this one -- this one we're looking at, this last one should contain all the pertinent information about the CAPA over the course of that three-and-a-half years. Right?

A. Right. It should.

Q. So this would be a good source for the history and the chronology of events that

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took place during the course of this CAPA investigation. Right?

A. Yes. Correct.

Q. And the information that's in here, is this information that you would have put into the CAPA, or did you derive information from other sources as well?

A. Both. And the information was -- that was placed -- at least the initial information was placed in here, like I said, before I picked it up --

Q. Okay. So the part --

A. -- as a project lead, yeah.

Q. The part under the "Description," who would have put that in there?

A. I can't answer that question. Whoever opened this record.

Q. Who other than you would have had access to the CAPA, the document?

A. Any number of people. CAPA administrators and quality engineers and -- it's not something that only person gets record -- access to.

Q. So under the "Description," it

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says that "Medtronic MiniMed received a complaint call, Service Notification (SVN) 303925131, on September 18, 2012 by a customer describing an unusual behavior of the Paradigm insulin delivery system during manual prime/fill cycle."

Do you see that?

A. Yes, I do.

Q. Okay. And was -- to your knowledge, is that complaint the one that was associated with the video that we just played?

A. I cannot answer that question. I don't know.

Q. Okay. But there was some complaint that triggered it, and it was associated with the videotape, a video like that. Right?

A. Yes, correct.

Q. It goes on, "According to the customer, after filling the reservoir and connecting it to the infusion set," and it identifies that as MMT-8 66 Sure-T, Lot #5002095, "the reservoir was loaded into a model MMT-754 insulin pump and a manual prime sequence was started. The customer noted that the insulin

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started flowing through the cannula of the infusion set before the plunger of the pump physically engaged the stopper of the reservoir and that the insulin continued flowing after the manual prime cycle was aborted by the customer."

Do you see that?

A. I do.

Q. All right. And that's consistent with what we observed in that video, that the stopper of the reservoir, the plunger, was moving ahead of the slide screw. Correct?

A. Correct.

Q. And is it your understanding that there were some infusion sets that were returned for testing that were associated with this complaint?

A. Again, yes, I think so. I don't remember exactly.

Q. Do you remember that there was some testing that was done on those returned infusion sets and they couldn't reproduce the phenomenon?

A. Yes, I do.

Q. Okay. And do you recall that in

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fact it wasn't until -- I believe it was Mark Curtis actually noticed some diluent fluid, the fluid that's used in place of insulin for testing purposes, on the inside of the connector cap?

A. In one of his tests, yes. But I don't think they were necessarily the infusion sets returned from the customer.

Q. No. You're correct. They weren't. But it was sort of an incidental finding by him that he made after he realized that he probably hadn't filled the reservoir correctly?

A. Correct. Yes. I remember that.

Q. Right. And that the insulin spilled out from the -- or the diluent, the green fluid, spilled out from the vial when he disconnected the reservoir while it was underneath the insulin vial. Right?

A. Yes. While it was still connected to a pressurized insulin vial, yes --

Q. So --

A. -- or diluent vial.

Q. So he hypothesized that the insulin could be blocking the vents if it got

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spilled on the inside of the connector cap. Right?

A. So if it got spilled on the top of the reservoir --

Q. Right.

A. -- not removed and after that reservoir would be connected to the cap, then that insulin or fluid would be transferred into the P-cap membrane.

Q. And then he actually went and made a video demonstrating that phenomenon. Correct?

A. That's correct.

Q. And then that triggered a review of the returned insulin infusion sets where they developed a test to determine the presence of residual insulin on the inside of the caps. Correct?

A. Yes.

Q. And when they went back and they tested the returned infusion sets that were associated with this phenomenon, this complaint, they found in fact residual insulin on the inside of the connector cap. Correct?

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A. I don't remember exactly the findings, but yes. The test was developed, and Mark did some trials, Mark Curtis did some trials. I don't remember the details as to which ones he tested and what were the outcomes.
Q. Okay. But do you recall that at some point there were tests for residual insulin that came back positive, that they found residual insulin on the inside of the caps?
A. Yes.
Q. And then -- let's show -- this is Exhibit --
Do you recall that there was a video that was made to educate people within Medtronic about this phenomenon back in the spring of 2013? Do you recall that?
A. No, I don't.
Q. If you could look at -- if just look at the photograph of Exhibit 14.
- - -
(Deposition Exhibit No. AA-14, Video, was marked for identification.)
- - -
BY MR. HAVERTY:

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Q. Yeah, you see it on the screen.
Do you recall seeing this video, Mr. Aleksandrovich?
A. Not at this point. If you show me the video, maybe it will refresh.
Q. I'm going to. So we'll play this right now. This is Exhibit 14.
- - -
(Video played.)
- - -
BY MR. HAVERTY:
Q. Yes. So have you ever seen that video before?
A. Never seen this video. It's a great video, and I'm ashamed that I've never seen it.
Q. I was going to ask you, is what's depicted on that video consistent with your understanding of how the vent blockage could occur and what the consequences of that would be?
A. Yes, it is.
Q. All right. And you were aware that based upon that testing and -- they were able to replicate the phenomenon, that that led

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to a situation analysis concerning the phenomenon?
A. Yeah. Again, I'm not exactly sure of the sequence of events, but they were able to replicate the phenomenon, yes.
Q. And can you tell us what a situation analysis is?
A. A situation analysis, to my knowledge, is a set of activities that -- you can call it initial -- initial attempt to a root cause analysis and also a risk assessment when there is something -- something out of the ordinary happens with the -- with a product, whether it's done by -- through a complaint from a customer or something found internally, it's basically initial risk assessment and initial data assessment, if you will.
Q. And that's sort of the first step in the process of an investigation, where you've got a hazard that's potentially identified. Correct?
A. Correct.
Q. I guess that's why it's called a situational analysis. You want to understand

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what it is that you're looking at initially to determine what steps you might want to take to investigate further. Right?
A. That's right.
Q. And depending upon what the initial assessment of the situation analysis is, that could lead to a health hazard evaluation. Correct?
A. It can. Like I said, it can lead to any number of things.
Q. Okay. Other than a health hazard evaluation, what would a situation analysis -- or strike that.
Is a health hazard evaluation an escalation from a situation analysis?
A. I can't answer. I'm not super familiar with that procedure, again, which -- what is an escalation, what is the -- what leads into that and what is the consequence of what.
Q. But you would agree with me, though, that opening a CAPA is sort of the ultimate escalation from these types of complaints. Correct?
A. That I agree with.

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Q. And as a matter of fact, at Medtronic diabetes, is there a CAPA board?
A. There is a CAPA board.
Q. And the purpose of the CAPA board is to make decisions as to whether a CAPA is required, given a particular situation. Right?
A. Correct.
Q. So you would have these various escalations leading to a decision about whether or not to submit an issue to a CAPA board to determine whether a CAPA should be opened. Right?
A. It's -- yes. I guess -- I guess I can agree to that, yes. The situation analysis is submitted to the CAPA board to determine whether it warrants a CAPA or not.
Q. And part of the health hazard evaluation that might perhaps be an escalation of a situation analysis is to determine what the risk is to the patients. Correct?
A. Yes.
Q. And I want to look at -- looking back at Exhibit 2, if you look at page 3 of Exhibit 2, which is Bates stamped 028985 in

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Brackin. The "Priority Rationale" here for this CAPA "was set as high due to the following reasons: Product is in the field" and "Patient safety risk is high do to the following reasons."
Do you see that?
A. I do.
Q. And did you understand that the evaluation of the risk to patients was the -- the danger was considered to be severe, even if the risk was low that it would occur?
MR. MERRELL: Objection to form.
THE WITNESS: The consequences of this phenomenon can be severe, yes, I will agree to that.
BY MR. HAVERTY:
Q. And that's because it could lead to the unintended and unknown -- unintentional delivery -- over-delivery of insulin into a patient's body. Correct?
A. Correct.
Q. And that could lead to either coma or death ultimately. Right?
A. Yes. I'm not a medical professional, but yes. Nothing good can come

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from an over-delivery of insulin.
Q. Right. So do you recall when it was that you first did get involved with this investigation?
A. I don't exactly, no.
Q. Okay. Well, if you look at Exhibit 2 for identification, it looks like -- we agreed that the date it was created was April 30th of 2013. And if you look at the second page, it has you listed as the owner.
Do you see that?
A. That's correct.
Q. And your team members were Mark Curtis, John Duarte, Benjamin Grover, Charlyn Lu and Matt Weiner. Correct?
A. Correct.
Q. So the owner means you're the leader on this. Right?
A. Yes.
Q. So when the CAPA is opened, it was assigned to you. Correct?
A. I don't -- again, I don't remember. It doesn't mean -- me being here as an owner doesn't mean that I was assigned it from

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the beginning. Owners do change on CAPAs, and these documents do change.
Q. Do you recall how it was you first got involved with this CAPA?
A. I do. Yeah. I got called into a meeting to quality -- one of the quality directors at the time and was presented with this project and asked to -- or assigned to take the lead on this.
Q. Do you recall anything else you were told about that?
A. About what, I'm sorry?
Q. Yeah. Did you -- what did you understand the reason the CAPA was being opened?
A. The reason for -- for that is the risk is high and despite the occurrence being low, and there is something that makes this happen, and we need to investigate and alleviate it.
Q. And did you have an understanding at that point in time what the problem was, what the risk was?
A. What the risk was and what the problem was, yes.

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Q. So at that point when you got involved, had the investigation already been done, they identified the problem, they replicated it, they had done all that investigation, and they realized that a CAPA needed to be opened?
A. Correct.
Q. At the time when you got called into this meeting, had the CAPA been opened at that point or would you be -- were you discussing this because there was an intent to submit it to the CAPA board? Do you recall?
A. I believe it had been opened by then.
Q. Okay. And do you recall why it is you were assigned to it?
A. Because that fell into my direct responsibility from a product and process and supplier relationship perspective.
Q. And what did you do initially when you got involved in this CAPA? What steps did you take?
A. Hard to remember, but we set occurring meetings, and we started looking at

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different things. We started pulling team members in, and essentially started investigating in many different directions.
Q. If you could take a look, please, at Exhibit 8.
- - -
(Deposition Exhibit No. AA-8, PowerPoint, "Prime/Fill Anomaly Review 3-21-13," Bates stamped MDT-BRACP-0067966 through MDT-BRACP-0067973, was marked for identification.)
- - -
MR. MERRELL: 8.
THE WITNESS: 8, I'm sorry?
BY MR. HAVERTY:
Q. 8. Yes, 8.
A. 8.
Q. Do you have it there?
A. Almost.
MR. MERRELL: Sorry, we're just fiddling with the binder.
THE WITNESS: Dealing with a malfunctioning binder.
- - -

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(A discussion off the record occurred.)
- - -
BY MR. HAVERTY:
Q. Do you have that there?
A. I do, yes.
Q. Okay. It's a PowerPoint slide deck. Correct?
A. Correct.
Q. Have you ever seen this PowerPoint slide deck before?
A. I do not remember.
Q. You don't know who prepared it, do you?
A. I don't.
Q. Do you recall whether there was a -- any type of a presentation, a meeting, about the prime/fill anomaly review in March of 2013?
A. I don't remember that.
Q. Okay. Go on to the second -- second page. And it gives a "Background." It says, "Complaints from Europe on Insulin dripping out prior to plunger touching the Stopper." And it's, "Video sent from a Customer in Germany."

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And then, "Customer's sets arrived for analysis 1-31-13." And then, "P-cap Vent flow tested and found to be in spec." And then, "Detailed engineering investigation by Mark Curtis and January Duarte through February."
Do you see that?
A. Yes.
Q. And that's what we were just talking about a few minutes ago, correct, the sequence of events that occurred from the complaint in September of 2012. Right?
A. It appears so, yes.
Q. And is that consistent with your recollection of the events as they unfolded?
A. Again, I have a hard time remembering this, because I don't think I was involved in this project at that time.
Q. But at some point when you did get involved in it, you learned about the historical events. Correct?
A. Correct.
Q. And what was just described there, is that consistent with what your understanding was of the history?

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A. Yes, correct.
Q. And then the next page, it's "Engineering Analysis Results." And it says, "Root Cause Identified: Insulin drops wetting the membrane from inside create temporary block of membrane. Drops are most likely formed via improper reservoir filling technique." And "Preliminary experiments indicate a wet membrane may take 5 minutes to over 30 minutes to dry out while in the pump."
Do you see that?
A. I do.
Q. And it makes reference to a video. There was a video that Mark Curtis had made demonstrating this.
Is that your recollection?
A. Yes, correct.
Q. All right. And then the next point is, "Confirmation of Customer case." It was a "Test to detect dry insulin on the membrane developed." And then "Traces of dried insulin were identified on the returned sets."
Do you recall we talked about that earlier?

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A. Yes, I do.
Q. So that was consistent with what the history was that you learned about this phenomenon. Correct?
A. Yes.
Q. And then go to the next page, if you would.
This is a line graph that I believe you had -- you had somebody make for you. Correct?
A. Again, I don't remember if it was made at my request or it was made prior to that.
Q. Okay. Well, you see that it has the "Occurrence Rate" of "Prime Fill Anomaly EA05 Complaint Count" from January 2011 to February 2013.
Do you see that?
A. Yes.
Q. And by the way, let's talk a little bit about that.
One of the issues that came up was the issue of the coding of these complaints as prime/fill anomaly. Correct?
A. Correct.

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Q. And the problem that they had with that is the prime/fill anomaly, the EA05 code, was generic to more than just one particular problem. Correct?
MR. MERRELL: Objection to form.
MS. MARTINEZ: Objection.
THE WITNESS: That is correct.
BY MR. HAVERTY:
Q. So that's why it was difficult for them to determine what the actual incidence of this phenomenon was based upon the complaints and the coding. Right?
MR. MERRELL: Objection to form.
THE WITNESS: Yes. That is correct.
BY MR. HAVERTY:
Q. And we're going to get into this in a little bit more detail.
As a result of that, a new code was developed that was specific to this temporary vent blockage phenomenon. Correct?
A. Correct.
Q. Now, it's captioned at the bottom there, it says, "About 20% of complaints" -- this

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would be of the EA05 complaint code -- "indicate insulin dripping without plunger touching."
Do you recall that assessment?
A. No, I don't.
Q. Do you -- if you note that there's a beginning upward trend in these complaints beginning it looks like in around January of 2012, peaking in about October of 2012.
Do you see that?
MR. MERRELL: Objection to form.
THE WITNESS: I can see that on the graph, yes.
BY MR. HAVERTY:
Q. Do you have any idea why they would have began that upward trend and peaking ultimately in October of 2012?
A. No, I don't.
Q. Okay. If you go to the next page, it says, "Patient Risk - Known Cases of Harm." And it says, first bullet point, "Reviewed SVNs for the period of January 2011 to February 2013, for primary-fill anomaly and Low Blood Glucose (both hospitalized and non

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hospitalized) codes."
Next bullet point, "Additional legal received from Legal."
Next bullet point, "5 instances of customers experiencing inside Low Blood Glucose" at -- "(at varying levels of severity) were identified during the period." And then, "Details are tabulated in the next page."
And then it goes on and says, last bullet point, "Annual Occurrence is estimated at 91 cases per year," and that's "(20% times 457), or" about "0.02% of Active base (425,000), which is a Rare Occurrence."
Do you see that?
A. I do.
Q. Okay. Were you aware of that information around the time you got involved in this?
A. No. I was aware of the five instances of customers experiencing low BG.
Q. Okay.
A. But not about the rest of the data here.
Q. You were not aware of the

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estimate of 91 cases per year, this phenomenon?
A. No. I don't remember those numbers.
Q. Okay. Did you at some point become aware of that?
A. I did, but, again, maybe not about those numbers exactly.
Q. Okay. And by the way, going back to where we identified the SVNs, those are service notifications. Correct?
A. Correct.
Q. And those are documents that are created when a customer calls in with a complaint. Correct?
A. Correct.
Q. And they each have their own unique number. Right?
A. Right.
Q. If you go to the next page, please, and it lists the five SVNs, correct, that were identified where patients were hospitalized or had low blood glucose and were either hospitalized or not hospitalized. Right?
A. Right. I only see three numbers

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but five occurrences. Yes.
Q. Right. Because two of them don't have an associated SVN. Correct?
A. Correct.
Q. For whatever reason, nobody knows, I guess. Right?
A. Correct.
Q. But anyway, the first one was from September of 2012, and it notes that the complaint was "Low Blood Glucose Not hospitalized, suspected 50 units of over delivery."
Do you see that?
A. I do.
Q. And I think you said, you do remember the -- the information concerning the five cases that were identified. Right?
A. That is correct.
Q. And then the next one is dated 5/23/12, "Low Blood Glucose, hospitalized, Suspected 80 units" of "over-delivery."
Do you see that?
A. I do.
Q. And by the way, 50 units or

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80 units of over-delivery would be a pretty large dose of insulin, would it not?
A. Not exactly sure about dosage.
Q. Okay. It would probably depend upon the individual patient. Right?
A. Correct. Again, I'm not a medical professional, so I cannot really make those assessments.
Q. Okay. Then the next one is from February 22nd of 2011, and it's listed as a "Low Blood Glucose, hospitalized, suspected 200 units" of "over-delivery. Deceased a month later, correlation to be determined" and "Litigation Pending."
Do you see that?
A. I do.
Q. Do you ever recall any conversations about any of these five cases? Were you ever involved in any discussions?
A. These five cases, if I remember, they're mentioned in the CAPA, and the CAPA was actually opened based on these five cases.
Q. Okay. And -- okay. That's an interesting point that you make.

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What about these five cases drove the decision to open a CAPA?
A. The -- I guess the severity of these five cases.
Q. Right. And that's -- in fact, you've got one that was hospitalized with 200 units of over-delivery who died a month later. Right?
A. Yes. Suspected 200 units, yes.
Q. Yeah. And then the fourth case that's listed is from June of 2012, and it has "Low Blood Glucose, Hospitalized, suspected 85 units" of "over-delivery."
Do you see that?
A. Yes.
Q. And then the final one is from March of 2013, "Low Blood Glucose not hospitalized, suspected 75 units" of "over-delivery."
Do you see that?
A. I do.
Q. Do you recall a situation where a customer reported to Anthony Vicente that he had -- that he had filled his reservoir,

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attempted to prime his pump, and it only primed a couple of units when he expected 8 or 9 units, and that he woke up in the middle of the night and saw that his reservoir was empty? Do you recall that?
A. I recall that somebody made a complaint directly to Anthony Vicente at some social event or sports game. I don't exactly remember the details of the complaint.
Q. Do you know whether that was the March 14, 2013 SVN that's listed there as case number 5?
A. No. Like I said, I don't remember the exact SVN that that resulted in.
Q. And during the course of your work on the CAPA, in the investigation, did you have interactions with Anthony Vicente?
A. Of course.
Q. Prior to this time, your involvement in the CAPA, did you have any interactions with Anthony Vicente?
A. Yes.
Q. Why would you have a reason to interact with Anthony Vicente other than outside

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this CAPA?
A. On some other projects. Anthony Vicente takes care of SVNs, and sometimes there's data needed for this project or that project that only can come from him or people working in the same department with him.
Q. Okay. If you could go to the next page on Exhibit 8, so this appears to be a type of a risk assessment. Correct?
A. Looks like it, yes.
Q. Okay. Are you able to tell from this matrix what the estimated risk assessment was for this prime/fill anomaly? Is there any way to tell?
A. No, no, not really.
Q. Okay. If you look up at the top there, it's got "A33 - Loose Cap only Annual Frequency 0.3%."
Do you know what that's referring to?
A. I do.
Q. What is it referring to?
A. So A33 is a -- is a failure -- let's call it a failure code that is produced by

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the pump, I assume. And what I remember, there was a -- there was a project around that.
Q. Was there a CAPA, to your knowledge?
A. I think there was a CAPA. And I actually may have been briefly involved in that CAPA, very briefly.
Q. And what was your involvement in that CAPA?
A. I did some experiments on that while -- while they were looking for another engineer to take that over.
Q. And what experiments did you do?
A. So a loose cap test has to do with a portion of a pump housing that may become loose, and we did some experiments on different geometry on that.
Q. Now, on this risk matrix, it doesn't look like there's any evaluation of the risk from the prime/fill anomaly. Correct?
A. Correct. Not obvious, yes.
Q. Okay. If you go to the next page, again, it doesn't appear to be any analysis of the risk specific to the prime/fill anomaly.

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Correct?
A. Correct.
Q. And I think you said that you -- the CAPA had already been open -- you think the CAPA was already opened by the time you got involved in it?
A. That is correct.
Q. Do you know who presented to the CAPA board in order to get a CAPA open?
A. No, I do not.
Q. What was the -- anyway, if you could go back to Exhibit 2, to the CAPA -- the complete CAPA file.
A. Uh-huh. Yes.
Q. And look on page 2, the second page, under "Mitigation Comments," it says, "A Health Hazard Evaluation...2013-03...was performed to assess the risks and evaluate potential risk mitigation methods. The following steps were identified to be needed in order to mitigate the risk at hand."
First bullet point, "Customer communication letter-sent to current US Paradigm pump users."

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Next bullet point, "Healthcare Professional Letter-sent to physicians who have prescribed Paradigm pumps."
Next bullet point, "Distributor letter-sent to distributors and payers."
Next bullet point, "Wholesale letter-sent to wholesale partners."
And last bullet point, "In addition to all communications, a package insert is included with shipments of Paradigm pumps, reservoirs and Paradigm Infusion sets."
Do you see that?
A. I do.
Q. Okay. Would you agree with me that that was intended as the corrective action -- the corrective part of a corrective and preventative action?
MR. MERRELL: Objection to form.
THE WITNESS: It was the initial corrective action. Yes, I would agree with that.
BY MR. HAVERTY:
Q. And was there a discussion that in addition to the initial part of the corrective

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part of the CAPA, that there would be a preventative process designed to look at how you could mitigate the hazard entirely?
A. When you refer to discussions, at what point of time and at what -- in what settings?
Q. Well, when the CAPA was opened, what was the intent at that point, do you know?
A. Again, I don't remember, because I think CAPA was opened before my involvement.
Q. Okay. Well, did you come to understand what the purpose of the CAPA was once you got involved?
A. Yes.
Q. And what was the purpose of the CAPA?
A. CAPA -- purpose of the CAPA was to investigate and potentially implement something that will completely eliminate this phenomenon from -- from happening, or at least mitigate it to the point of very, very low occurrence.
Q. Right. And what we're talking about here in the mitigation comments, and we

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talked about that's the corrective part of the process, these would all fall under the category of the type of warnings that you would use for risk mitigation. Correct?
A. Correct.
Q. And again, as we talked about, that's the least preferred method of risk mitigation, if you can design the hazard out or if you can guard against the hazard. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: Again, it's -- it's depending on the situation. I -- there's -- I can't -- I can't say whether one is more important or more effective than another.
BY MR. HAVERTY:
Q. Okay.
A. It really all depended.
Q. Anyway, going back to the next page, we talked about this, I didn't finish up, I'm sorry for jumping around, we talked about the "Priority Rationale...was set as high due to the following reasons: " The "product is in the field," which means patients are being exposed to

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it. Correct?
A. Correct.
Q. And then "Patient safety risk is high do to the following reasons," and that's when we talked about the risk was relatively -- the severity of the risk was important. Correct?
A. Correct.
Q. And that's because "The failure can potentially result in over delivery of insulin leading to patient hospitalization" and "The failure can potentially result in under delivery of" insulation -- "insulin leading to patient hospitalization."
Do you see that?
A. I do.
Q. Now, we talked a little bit about how the over-delivery could occur, based upon the videos and what was shown in the videos.
Can you describe for us how the failure or the blocking of the vents could potentially result in an under-delivery of insulin?
A. To the best of my knowledge, once the phenomenon occurs and then pressure finally

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equalizes in the chamber, the pump will continue to drive the piston or the slide, by the slide not being engaged to the stopper on the reservoir will not result in any delivery of insulin.
Q. And that's because when the reservoir stopper begins to move on its own and the slide screw has to basically chase -- chase after it to catch up, there will be a gap between them. Correct?
A. Correct.
Q. So --
A. There is no physical connection between the -- between the slide of the pump and the plunger or stopper of the reservoir.
Q. So what could happen is that the reservoir moves to a certain point ahead of the slide screw, stops when the pressure equalizes, and then there's a lag from the slide screw, and it takes some period of time for it to catch up before it can continue to deliver insulin. Correct?
A. That is correct.
Q. And it all depends upon -- how long that period of time is all depends upon how

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large the gap is between the slide screw and the reservoir stopper when the reservoir stopper stops. Right?
A. That is correct.
Q. Now, one of the things -- if you could look at page 8 of the -- of Exhibit 2.
Actually, go back to page 6. Let's go there and lay a better foundation.
- - -
(A discussion off the record occurred.)
- - -
BY MR. HAVERTY:
Q. Okay. All the way at the bottom, do you see that? It says, "It is concluded that based upon the above described testing and observations," which we talked about a little earlier, "the prime/fill anomaly is caused by a blocked membrane and a contributing cause being the Reservoir filling process where an incorrect filling process can result in a blocked membrane. The contributing cause of an incorrect filling process will not be addressed as the filling process is dependent on the user and when the IFU

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is followed correctly there should not be any issues during the reservoir fill process. For this reason, this CAPA will only address the prime/fill anomaly caused by a blocked membrane. The blockage is most likely caused by a liquid (insulin or other) being present on the polyester side of the membrane. Liquid, when present on the polyester side of the membrane, seems to render the membrane impermeable to air which, in turn, traps air contained in the reservoir compartment of the pump. During a manual primary/fill cycle, the trapped air inside the pump housing gets pressurized and causes a premature movement of the reservoir plunger. Based on all factors and investigation results, the team concluded that the primary root cause for the temporary blocked P-cap membrane is" the "membrane material itself."
Do you see that?
A. I do.
Q. Okay. And that membrane material is part of the design of the P-cap. Correct?
A. Correct.
Q. So the goal of the CAPA then was

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you were not going to address the IFUs, or the information for users, which would be sort of like along the lines of a warning, you were going to redesign the materials in the connector cap to make sure that they could remain gas permeable in the event that someone does fill a reservoir improperly and insulin gets on the inside of the cap. Right?

MR. MERRELL: Objection to form.

THE WITNESS: Right. So partially due to the fact that IFUs had been updated by this point in time with warnings and we, team, company, did not believe that that is good enough. So we decided to take one step further and change something design-wise to either completely eliminate this from occurring, although you really can't theoretically, but at least take the possibility of occurrence to some minuscule number.

BY MR. HAVERTY:

Q. And I think you just said something that was important for me to follow up on.

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And that is that when you evaluated the mechanism of the failure mode and you understood how it could occur, you didn't believe that updating the IFUs and providing warnings was sufficient or adequate to mitigate this risk. Correct?

MR. MERRELL: Objection to form.

THE WITNESS: Not to 100 percent of -- to take care of problem.

BY MR. HAVERTY:

Q. Right. Because the IFUs and this filling process, this improper filling process, all involved humans who could easily make mistakes through inadvertence or inattention. Right?

A. Correct.

Q. So what you wanted to do was to make sure that to the extent you could was to design out the hazard entirely. Right?

A. That is correct.

Q. And not rely upon --

A. But --

Q. I'm sorry. Go ahead.

A. Correct. To design out the

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possibility of hazard occurring. Yes.

MR. HAVERTY: Cliff, do you want to take a real quick break here?

MR. MERRELL: Sure.

THE VIDEOGRAPHER: We are now going off the record, and the time is 11:36 a.m.

- - -

(A recess was taken from 11:36 a.m. to 11:57 a.m.)

THE VIDEOGRAPHER: We are now going back on the record, and the time is 11:57 a.m.

BY MR. HAVERTY:

Q. Mr. Aleksandrovich, if you could look at Exhibit 1, please, pull that up.

I just want to lay a foundation for this.

- - -

(Deposition Exhibit No. AA-1, Slide, "P-cap Infusion Sets Prime Fill Anomaly CAPA PR#158416," Bates stamped MDT-BRACP-029894, was marked for identification.)

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- - -

BY MR. HAVERTY:

Q. Got that?

A. Yes, I do.

Q. Do you recognize this timeline?

A. No. I've never seen this timeline.

I stand corrected. I recognize the timeline. I've never seen this particular slide.

Q. Okay. So you didn't create this. Correct?

A. I didn't.

Q. Could you just take a moment to review it, because I want to use this as a foundation for some questioning, you know, along the way.

And just take a look at the timeline and see if it comports with your recollection of the events related to this CAPA.

MR. MERRELL: It's actually really hard to read --

THE WITNESS: Yeah, it is very hard to read.

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MR. HAVERTY: Yeah, I know it is.
MR. MERRELL: -- Kevin.
MR. HAVERTY: I know it is, and I apologize for that, but that's how it came to me.
MS. MARTINEZ: Here.
MR. MERRELL: Do you want look -- there's another version.
Do you want to look on a computer, it might be easier to see?
MR. HAVERTY: Oh, okay.
MR. MERRELL: Would that be helpful.
MR. HAVERTY: I didn't think it was easier to see on the computer.
THE WITNESS: I can see most of it. Some things there's just --
MR. MERRELL: It may not be. I'm just offering it. It's at least larger.
MR. HAVERTY: Yeah. You just need to have your prescription checked, Cliff.
THE WITNESS: No, no. It's okay. Resolution gets lost anyways.

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MR. HAVERTY: I spent about a half an hour trying to make sure that I got the maximum resolution, because I agree, it's terrible.
THE WITNESS: Good to go.
BY MR. HAVERTY:
Q. Yeah, I noted, just for the record, that you made some notes on that copy?
A. I did.
Q. What did you put on there? Just so we can have it on the record.
A. Just abbreviations -- just abbreviations to understand -- so I can understand what those blocks are. Not very good to see.
Q. Okay. But does that comport with what your recollection of the timeline was for the development of the new membrane material?
A. It does.
Q. I just want to put that aside for right now but use that as a handy touchstone for -- for going forward.
Before we do that, excuse me, it notes that the CAPA start date was sometime

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before May of 2013. Right?
A. Correct.
Q. And then there's a field corrective action/health hazard evaluation noted in May of 2013. Right?
A. Correct.
Q. And that's one of the things that led to -- strike that.
Then it looks like May into -- sometime in early May there's an "Extension Request #1" for the "Investigation Phase, Extension to summarize root cause findings in ER. New due date: 6/28/13."
Do you recall that?
A. I don't recall that, but I see that and I can understand what this refers to.
Q. I was going to ask you that. What does it refer to? Why was an extension needed?
A. Because sometimes the originally planned time for certain tasks is not sufficient enough and -- due to many things, possible things.
Q. Okay. The -- I'm sorry.

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So does that mean that you didn't anticipate being able to identify the root cause from the engineering report until the end of June of 2013?
A. That means that whoever filed that extension, it might have been me, it might have been somebody else, I don't recall at this moment, that means that whoever did that needed more time to finish thorough investigation.
Q. And to determine -- to come to a conclusion about what the root cause was of the problem. Correct?
A. True, yes.
Q. Okay. And then it looks like the root cause was identified at the end of June, consistent with that extension request. It's a big yellow box. Right?
A. Correct.
Q. And it says -- yeah. It says, "Root Cause. The primary/fill anomaly is caused by a blocked membrane. The blockage is most probably caused by a liquid (insulin or other) being present on the polyester side of the membrane. Liquid, when present on the polyester

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side of the membrane, seems to render the membrane impermeable to air which, in turn, traps air contained in the reservoir compartment of the pump. During a manual primary/fill cycle, the air trapped inside the pump housing gets pressurized and causes a premature movement of the reservoir plunger."

Is that your recollection of what the root cause was that was ultimately identified?

A. Yes. As documented.

Q. Okay. If you could -- and I apologize for bouncing around, but if you could go back to Exhibit 2, please, the CAPA report, and I want to direct your attention to page 4.

On the heading it's "Investigation Summary."

Do you see that?

A. Yes.

Q. And then, "Investigation started with testing of the returned infusion sets and, also, some testing of similar products."

You see we talked about that a little bit earlier, right, the returned products

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from Europe?

A. Right.

Q. And then the next paragraph says, "Based on historic knowledge (CAPA QIR09-006), it is known from the failure like the one reported by the end user (insulin flow prior to physical engagement between the pump plunger and" the "reservoir stopper) is caused by a completely or partially blocked vent membrane on the P-cap."

Do you see that?

A. I do.

Q. That -- when you're talking about based on historic knowledge and identifying that CAPA there from '09, is that -- is that referring to the Lot 8 CAPA?

A. I'm not sure what this CAPA number refers to and what this CAPA number is assigned to.

Q. Are you aware of what the historic knowledge is that they're referring to?

A. Yes. That is Lot 8 related, the historic knowledge, the description of the failure mode.

Q. Right. Yeah. So it goes on, it

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says, "As it was discovered from the investigation during QIR09-006, the blocked membrane was caused by a deposit of silicone oil."

That's the Lot 8 situation, is it not?

A. It is.

Q. It says, "This oil has been removed from the manufacturing process. Also, all questionable units returned during investigation phase of QIR09-006 remained blocked after return to Medtronic. Contrary to that, all units returned during investigation phases of this project demonstrated acceptable flow through the P-cap membrane when tested in MiniMed's lab. However, during the testing, the person performing the test noticed a small green diluent stain, inside the P-cap, on the polyester layer of the membrane."

And then it goes on to say, "(Green diluent is a test media of choice in MiniMed's lab environment.) Upon close review of the stain it was determined that the stain was residual diluent spilled onto the reservoir's

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Snapcap during filling from the insulin vial, and when P-cap was attached over the Snapcap, the green diluent was transferred onto the membrane inside the P-cap."

You recall that was the Mark Curtis situation. Correct?

A. Correct.

Q. And it resulted from Mark Curtis actually performing the same improper filling process as some of the other patients who had complained about the prime/fill anomaly. Correct?

A. It appears so, yes.

Q. So Mark Curtis, one of the -- one of Medtronic's own engineers, did the same -- made the same mistake as customers were making that was resulting in this prime/fill anomaly. Right?

MR. MERRELL: Objection to form.

THE WITNESS: I'm not sure if he made the same mistake during this investigation. He simply observed diluent. How it got there remains unknown at this point.

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BY MR. HAVERTY:
Q. Well, but it goes on, it says, "Residual...spilled onto the reservoir's Snapcap during filling from the insulin vial."
And you know that that was because it was -- the insulin vial -- excuse me, the reservoir was disconnected from the transfer guard while the insulin vial was on top. Right?
A. Again, I am not -- I cannot attest and I have no idea how exactly it happened during the event described in this particular paragraph.
Q. Okay. If you could go to -- if you go to page 8 on Exhibit 2.
Do you have that?
A. Yes.
Q. Okay. This page is captioned "Action Summary." It has "Action Plan: The goal of the CAPA is to eliminate the possibility of the PCAP venting membrane to become temporarily blocked if liquid is introduced to the inside of the PCAP. Membrane material replacement is necessary to eliminate such issue. An alternate membrane material was selected."

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That was the ultimate goal of the CAPA, was it not?
MR. MERRELL: Objection to form.
THE WITNESS: The ultimate goal of the CAPA was to determine a solution to the problem to eliminate the root cause. So this particular page states that solution was identified, yes.
BY MR. HAVERTY:
Q. And in this particular thing, as least as of the closing of this CAPA, it was -- the solution that was generated was an alternative membrane that could remain gas permeable even when wet. Correct?
A. Correct.
Q. And we're going to get into this a little bit, but that wasn't the only alternative that was explored during the course of this CAPA. Right?
A. The only alternative explored as a solution after investigation had completed.
Q. Well, but I'm saying, but during the course of the CAPA, were there other alternatives that were explored, such as venting

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the reservoirs in the pump?
A. It was discussed but quickly discarded.
Q. Okay. Why was it quickly discarded?
A. Because it's -- it is very, very challenging from the engineering and manufacturing standpoint.
Q. Why was it challenging from an engineering -- strike that. Let me make sure that we're on the same page.
What I'm talking about is, was it discussed that there could be some type of either a redundancy in the pump itself or some type of redesign of the pump that would allow venting?
A. To my recollection, again, it was briefly discussed. And due to the difficulties it would present to -- and the time frame it would present to -- and try to implement something like this, it was not considered as a solution.
Q. What time frame did they estimate it would take if you were to pursue a redesign of the pump itself or create a redundancy in the

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pump itself that could eliminate this hazard?
A. I don't remember exactly, but three to five years easy.
Q. And in this particular case with the membrane redesign, it took over three-and-a-half years. Correct?
A. To completely implement it, yes.
Q. Okay. But anyway, according to the action plan on page 8 -- and I'm just -- I'm not going to go down all of these. We'll follow up a little bit later. But the first thing was to "Identify Alternative Materials" and the due date for that was estimated, at least as the CAPA opened, October 15th of 2013. Right?
A. Right.
Q. And by the way, who was it that set these dates? Was it you as the CAPA leader?
A. At this point then, it was me, yes.
Q. Do you know how you settled on October 15, 2013 as an expected due date for identifying alternative materials?
A. Based on inputs provided by various team members and suppliers and my

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experience and other factors.
Q. And at this point in time, had you been in contact with Unomedical concerning the issues and the need for redesign of the membrane material?
MS. MARTINEZ: Object to the form. At which point in time?
THE WITNESS: Yes. We were in contact with Unomedical throughout the entirety of this project.
BY MR. HAVERTY:
Q. And I think, without going into a whole lot of paperwork on it, but I think you were concerned about what the basic problem was with the membranes, whether it was an aging process or whether it was the manufacturing process that allowed this material to become gas impermeable if wet. Correct?
A. Correct. We considered those.
Q. You explored a number of different options. And then you realized that it was the material itself and not any of the manufacturing processes or the age of the material. Right?

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A. Right, correct.
Q. If you could look at Exhibit 15, please.
- - -
(Deposition Exhibit No. AA-15, Email chain, top one dated May 21, 2013, Bates stamped MDT-BRACP-0050917 through MDT-BRACP-0050922, was marked for identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. Do you have that?
A. Yes.
Q. It's an email from you to Sara S. Harboe dated May 21, 2013.
Who is Sara Harboe?
A. She was -- I don't know if she still is, but she was an employee of Unomedical.
Q. Do you know what her job was?
A. No, I don't recall.
Q. Going to the body of this, you noted, "Attached is a graph summarizing the testing we've done on the historical samples that

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we had on hand."
And then it goes on a couple sentences later, it says, "As you can see, somewhere in 2009 we lost the ability to flow any air while wet. It is not a design requirement for the membrane but this is a phenomenon that we'd like to investigate."
Do you see that?
A. I do.
Q. What was your working theory at that point? Did you have any idea why in 2009 the ability to flow air even when wet was lost?
A. Yeah. It was part of the investigation of the historical samples to determine if the -- there was a change in the material properties that caused such phenomenon.
Q. And did you ultimately find that there was one or there wasn't?
A. We never found if there was one.
Q. Okay. So do you have any idea what it was that was unique to 2009 that you began to lose this gas permeability?
A. No. We were never able to determine it.

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Q. Do I understand from that that the historic samples that you tested that were from before 2009 were still able to be gas permeable even when wet?
A. Some of them were. Yes. If I remember correctly, some -- some samples were able to flow while wet, yes.
Q. Okay. And was that sort of random, you know, unpredictable, or were you able to identify any particular characteristics of those sets that allowed them to remain gas permeable?
A. Completely random. There was -- there was no correlations determined or anything in that aspect.
Q. So that would be another factor that would lead you to want to redesign the membrane material entirely, to eliminate any issue, even though some random samples could still remain gas permeable. Correct?
A. That is correct.
Q. Anyway, going back to Exhibit 2, the CAPA report, and back on page 8 --
A. Uh-huh.

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Q. Step 2 on the "Action Plan" was, you wanted to validate the assembly process using new material, and the estimated due date for that was May 30th of 2014.
Do you see that?
A. I do.
Q. Okay. How did you come up with that date of May 30th of 2014?
A. Again, based on inputs from customer and my team members and my experience.
Q. Okay. So what would happen is that you would expect or you were hoping to identify alternative materials by October 15th and then have them completely validated in the manufacturing process by the end of May of 2014, about six months later. Right?
A. Correct.
Q. And when you talk about validating the assembly process, does that mean actually manufacturing samples of the new material?
A. That's part of validating --
Q. What else --
A. -- the process.

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Q. What else is part of validating?
A. Part of validating is to determine the process -- first of all, whether there is a process, and then whether that's -- that process is capable of manufacturing what's -- what's expected, what in certain ranges with certain outputs. And also to determine the process range within -- within which we can control that.
Q. And let me ask this question: Did you -- during the course of this CAPA, did you have anybody who was a materials science person involved?
A. No.
Q. Okay. Are there any materials science people at Medtronic?
A. I can't answer that question. Probably there are some, but we never involved a specifically materials science person in this project.
Q. Is there a particular reason why you didn't consider consulting a materials science person?
A. Because, yeah, we didn't think there was a need to do that.

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Q. Did you know at the time when you were making this plan that there likely would be some type of material out there that could remain gas permeable even when wet?
A. I don't exactly remember the -- the correlation at which point we determined that there is a material out there as compared to this plan.
Q. By the way, I should have laid this foundation a little -- a long time ago.
But when talking about the membrane material which has the vents in it on the inside of the cap, it's actually a two-layer material, a two-layer membrane. Correct?
A. The material previously used is constructed that way.
And I would like to correct you. There's no vents opening in the membrane itself.
Q. Right. The vents are in the cap itself. Correct?
A. The vents are in the plastic house of the P-cap, yes.
Q. And the membrane goes on the inside of the P-cap. Correct?
A. Correct.
Q. And it's a two-layer membrane. The outside layer is a hydrophobic PTFE. Correct?
A. On the -- we're talking about the previously used membrane.
Q. Yes. Yeah, the one -- the one that was in use back in 2013.
A. Yes, that is correct.
Q. Okay. And that's what was called hydrophobic, meaning it repels water, it repels moisture. Correct?
A. Correct.
Q. And the bottom layer of the membrane which faces inside the cap, it was made of an unwoven polyester fiber. Correct?
A. Correct.
Q. Okay. And that was the issue, it was the polyester portion of it that could become gas impermeable if it got wet. Correct?
A. That is correct.
Q. If you could look at -- make sure I find this one. Give me one second, please.

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Exhibit 18, please.
- - -
(Deposition Exhibit No. AA-18, Email dated June 08, 2013, Bates stamped MDT-BRACP-0067490, was marked for identification.)
- - -
THE WITNESS: Go ahead.
BY MR. HAVERTY:
Q. This is an email from Benjamin Grover to you, among other people. Correct?
A. Yes.
Q. Dated June 8, 2013. And it looks to me, and correct me if I'm wrong, that there was a theory that was tested about whether if you flipped the membrane so that the PTFE, the hydrophobic section of the PTFE, was on the inside of the cap, whether you could still -- whether it would remain gas permeable even if it got wet. Correct?
A. Correct.
Q. That was a theory that was tested. Right?
A. Yes, that is correct.

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Q. And I take it from this email from Mr. Grover that that didn't work either. Right?
A. That is correct. It didn't.
Q. So that was -- that was a solution that was basically tested and rejected. Correct?
A. Correct.
Q. Okay. Going back to Exhibit 2, again, on the "Action Plan."
And you've got number 3 is "Design Review" is due 4/21/2014. Right?
A. Yes.
Q. What is the design -- what is the design review process?
A. Design review is a -- is a procedural process as part of the Medtronics quality system where whenever the change is being introduced, it needs to be reviewed and agreed upon by a multifunctional team before proceeding and needs to be documented as such.
Q. So that, even though it's step 3, it actually was due a month before the validation with the new material. Correct?

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A. Correct. Because these steps can happen in -- in parallel. That's why.
Q. Okay. But you would -- you would -- you would have to complete your design review of the new material before you would send out for validation, wouldn't you?
A. Not necessary.
Q. Why not?
A. Design review is not required to initiate a validation. Design -- design review is required to release something new into production.
Q. And for the purposes of validation could be one of those reasons for releasing it into production. Right?
A. I'm sorry. I'm not clear on the question. Can you ask again, please?
Q. I'm sorry. I'm not an engineer, so I'm trying to wrap my head around this process.
A. That's -- that's fine.
Q. You identify alternative materials in October of 2013. That's your goal. And then you develop the material. And then you

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want to validate it by actually manufacturing it in a process. Correct? And make sure that it meets the specifications that it's designed for. Right?
A. Correct, yes.
Q. But you actually have to design it before you can create the material, and then create a process to validate it. Right?
A. That is correct.
Q. And that's what I'm trying to understand is wouldn't -- wouldn't you be reviewing the design of it before you actually tried to put the material into process through validation?
A. So again, there are different ways to approach this. At this particular case, we took a risk and asked supplier to start validating once we've identified the material. And then we did the design review as a formal conclusion, if you will, for this -- and again, this was not a final design review. This was the final -- this was design review aimed to review the design intent, not to -- not to release the material to production.

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Q. And we're going to get into this in a little bit more detail shortly, but when you talked about you took a risk with a manufacturer, you meant you had actually done some testing on a number of materials, about five different materials. Correct?
A. We started with five and then we reduced it to three and further reduced it to two, yes.
Q. And that was based upon the characteristics of how well they would allow air to flow when wet. Correct?
A. That and also how -- how well they behave in a high-volume manufacturing environment, considering the machinery we use.
Q. Right. I think some of them you found that they were too fragile. Even if they were good at remaining gas permeable, they were too fragile to actually undergo the manufacturing process. Right?
A. That's correct.
Q. But anyway, if we go back to the "Action Plan," you had step 4 to "Qualify New Material on the Product Level -- Due:

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4/28/2015."
So that would be a year after you validated the assembly process. Right?
A. Right.
Q. Meaning when you're qualifying the new material on the product level, you validated it, you know that you can manufacture it to the specifications, and then you need to know whether or not you can do it on a large manufacturing level. Correct?
A. Not exactly like that.
So step 2 in the plan and step 4 are two different -- distinctly different manufacturing processes. Step 2 refers to what we call the P-cap assembly --
Q. Okay.
A. -- where a plastic P-cap housing is populated, if you will, with the membrane and the needle. That's one manufacturing process. It needs to be validated separately.
And the product level validation is where the assembled P cap, or P cap assembly, is assembled onto an infusion set.
Q. Okay.

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A. And then he infusion set tested as a part of the system to -- to validate the changes.
Q. Got it. So that would be the complete assembly process at that point. Correct?
A. Correct, correct.
Q. So by that time you would have -- you hoped to validate the assembly of the P-cap with the new membrane material by itself and then did the further step of assembling the entire product. Right?
A. That's correct.
Q. Would there be a separate validation for that process, or was that just the qualifying it on the product level?
A. In this particular case -- and, again, I don't remember how exactly we executed that, but in this particular case, it did not require a full validation of the process, just to -- how it affected the process with the change.
Q. Because you had -- it identifies it in step 2 that you've got a highly customized,

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fully automatic machine for assembling these P-caps. Correct?
A. Correct.
Q. So you wanted to make sure that you didn't impact the equipment that's already in place and have to redesign that or retool it to deal with the new material. Correct?
A. Absolutely. Yes.
Q. What you needed to do is make sure that you had a material that would fit within the already-existing manufacturing process. Right?
A. Correct. At this point, that was the case.
Q. Okay. If you could take a look at -- strike that.
Before we go there, and then step 5 was "Regulatory Submission," and that was estimated at that time to be submitted on or about July 17th of 2015. Correct?
A. Correct.
Q. So you were anticipating at this point that -- about a two-year process between identifying the problem and alternative materials

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and getting FDA approval. Correct?
A. Correct.
Q. And what was the basis or where did you derive that date of July 17, 2015 as your expected date for submission to regulatory?
A. Based on the completion -- on estimated completion of the previous steps, validation and validation testing and verification testing and so on and so forth.
Q. And what you have here, this action plan, is that part of your responsibility as the CAPA leader at this point to come up with these dates?
A. That is correct.
Q. And are these dates submitted to the CAPA board so that they become like deadlines for you to -- for them to evaluate how well the CAPA is moving along?
A. That is correct, yes.
Q. And you mentioned before that from time to time you may have requested extensions of these dates.
Would that have to go to the CAPA board for approval?

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A. I think -- there are different ways of extension approval process. And each subsequent extension requires more strict review and approvals, if you will, than the previous one.
Q. Okay. So whenever you make your initial dates, you want to make sure that you have the maximum amount of leeway in order if an extension is going to be needed, because you're going to have to have increasingly significant justifications for an extension. Right?
MR. MERRELL: Objection to form.
MS. MARTINEZ: Objection to form.
THE WITNESS: When I create -- this is, in essence, a project, and a CAPA leader is a project manager. A job of a project manager is to estimate to the best of abilities and knowledge the durations of the test in the project, and this is exactly what I attempted on this one.
BY MR. HAVERTY:
Q. By the way, I meant to ask you this, and I should have asked it a while ago, who

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is Sandra Perez?
A. Sandra Perez is a CAPA coordinator or CAPA analyst at Medtronic.
Q. Okay. What is the job of a CAPA analyst?
A. To help us to make sure that CAPAs stay on track and help us with the reporting software, which is very complicated.
Q. And there was another person I wanted to ask you about, let me see if I can find this, Andreasen, what's his first name?
A. Andy.
Q. Andy Andreasen. Who was Andy Andreasen?
A. Andy Andreasen was a quality manager back at the time.
Q. Okay. What was his role, if any, in this CAPA?
A. I think he was one of the initial approvers on the CAPA tasks.
Q. Okay.
A. Reviewer/approvers, if you will.
Q. Meaning what we were just talking about, the action plan? Would he be one of the

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approvers on that, do you know?
A. Andy Andreasen left the company while this CAPA was in process, so I don't remember if he approved the action plan or it was somebody else.
Q. Okay. I just saw his name on the documents earlier and wanted to know who he was.
A. Yeah.
Q. Who else were approvers on this CAPA plan?
A. They changed during the course of the CAPA, but various quality managers and functional managers and independent reviewers.
Q. Was there any person in particular who you would have reported to during the course of this CAPA?
A. Are you referring as the one over -- as a manager to me or --
Q. Yes, yes.
A. Well, I have my functional manager, and I also reported this to CAPA reviews, periodic CAPA reviews, and sometimes even -- even our CEO does a CAPA review.
Q. Your CEO, I'm sorry, did you say?

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A. Yes.
Q. Okay.
A. Yes.
Q. Do you know whether the CEO is -- this is of Medtronic Diabetes or MiniMed?
A. Correct.
Q. Do you know whether the CEO of MiniMed ever reviewed this CAPA?
A. Yes. I know that he has. He had.
Q. Okay. Do you know on more than one occasion?
A. On an occasion -- on an occasion that there is such thing that is called aging CAPA, there are -- that have been open for longer than anticipated, let's put it this way. Yeah.
Q. Okay. And what's the purpose of the CEO reviewing an aging CAPA?
A. Because CAPA is a big part of reporting to regulatory bodies, and that's important that they stay on time. And they progress and then they close eventually.
Q. And are you aware of the fact that the FDA, even in a warning letter that

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they've issued to Medtronic, talked about CAPAs that were open for too long and never closed or not closed properly? Do you recall that?
MR. MERRELL: Objection to form.
THE WITNESS: I'm not familiar with the content on the -- of the warning letter.
BY MR. HAVERTY:
Q. Okay. Were you aware that there was a warning letter that was issued in 2013, September of 2013?
A. I am aware of that, yes.
Q. Were you involved at all in the responses to that warning letter to the FDA?
A. No, I was not.
Q. Did you ever review that warning letter?
A. No, I didn't.
Q. If you could look at Exhibit 10, please.
- - -
(Deposition Exhibit No. AA-10, PowerPoint, "Prime/Fill Anomaly Review 4-24-13," Bates stamped MDT-BRACP-0069182

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through MDT-BRACP-0067256, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. Do you have that?
A. I do.
Q. This is another PowerPoint slight deck titled "Prime/Fill Anomaly Review" dated April 24, 2013.
Have you ever seen this slide deck before?
A. Give me a second, please.
Q. Sure.
A. I recognize portions of it. I cannot say exactly if I've seen this in its entirety together in this -- in one presentation.
Q. Okay. Let me ask the question this way: During the course of this CAPA, did you ever prepare any PowerPoint presentations that you presented?
A. Yes, I did.
Q. How many did you prepare?
A. I can't -- I don't remember.
Q. All right if you had done a

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PowerPoint presentation and you prepared it, did you typically put your name on it?
A. I would, yes.
Q. All right. Well, as of April 24th of 2013, would you have been involved with this prime/fill anomaly review at that point, do you know?
A. Again, I don't remember exactly when I was assigned to this.
Q. Okay. We know that the CAPA was opened on April 30th of 2013.
So you don't remember whether you had any involvement prior to the opening of the CAPA or not?
A. And even after opening the CAPA. I don't remember if I was on the CAPA right from the beginning.
Q. Okay. Well, in any event, if you look at page 2 of that, it has a slide that's called "Process Flow."
A. Yes.
Q. First of all, do you know what that's referring to?
A. This particular refers to some

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process, that -- the steps of the process and sequence of those.
Q. So the first one is, it's "Event Notification."
I assume that refers to -- or correct me if I'm wrong, that refers to the first complaint about this phenomenon. Right? That's how Medtronic was notified?
A. It looks like this. I wouldn't like to assume. This looks like a process flow for a CAPA creation and CAPA reporting.
Q. Right. And so step 2, it looks like "Obtain product from Customer." We talked about that, where there were some returned infusion sets. Right?
A. Right.
Q. And then the third step, "Standard Failure Analysis and/or Engineering Study."
We talked about that, there was an engineering study, they identified what the issue was. Right?
A. Uh-huh, yes.
Q. And then the next step is

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"Confirm Failure/Understand Implications/Understand Root Cause."
We -- that was identified as well. Correct?
A. Correct.
Q. And then it has "Risk Analysis and/or...(Health Hazard Evaluation)."
That -- was that done by the time you got involved in the CAPA, do you know?
A. It was, yes.
Q. Okay. And then the next step is "CAPA decision -- QIT board."
So from what you said -- told us a little bit earlier, all of these steps ultimately led to a decision because of the information that was gained from it to submit this issue to a CAPA board to see whether a CAPA was appropriate to be opened. Correct?
A. Correct.
Q. And because you got involved in it ultimately, and we saw from the Exhibit 2, a CAPA -- a decision was made that the situation was significant enough to warrant a CAPA. Correct?

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A. Correct.
Q. All right. And then the next step after the submission to the CAPA decision --
And by the way, the QIT board is the quality improvement team board?
A. Correct.
Q. Is that the same thing as what we've been referring to as the CAPA board?
A. No, it's not.
Q. Okay. So that's a separate board then. Right?
A. Correct, yes.
Q. So do these decisions about whether to open a CAPA go to both the CAPA board and the QIT board?
A. I don't exactly know how the process works.
Q. Okay.
A. The QIT is the first line of defense, if you will, and then CAPA board.
Q. Got it.
So if it goes to the CAPA board, that means it's already gone through the QIT board?

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A. Yes. That's -- it does.
Q. And that means that the QIT board felt that the situation merited a decision about whether to open a CAPA. Right?
A. Right. QIT board made a decision that there is an anomaly that's worth looking into in that aspect.
Q. The next step is field correction -- "Field Corrective Action Decision -- Quality Assurance plus Regulatory Affairs plus QIT Board." Correct?
A. Yes.
Q. And a field corrective action is something like a "dear healthcare provider" letter? That's one thing?
A. One of the things. Can be a number of things.
Q. What else could constitute a field corrective action?
A. It could be a recall. It could be -- it could be a product hold. It could be a seizing of shipments. Many different things.
Q. Okay. All right. Then the next step was to create a "Field Corrective Action

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Plan."
And I guess -- I'm assuming that was assigned to regulatory affairs, do you know?
A. From this process flow, it looks like that.
Q. By the way, over to the right there, it says vice president -- right between confirming and understanding the root cause and the risk analysis and HHE, there's a step to the right that says, "VP Quality Assurance to inform Corporate ASAP on potential field corrective action items."
Do you see that?
A. I do.
Q. Do you know what that's referring to?
A. Referring to corporate communication means?
Q. Yeah. Do you know why the VP of quality assurance was to inform corporate as soon as possible on potential field corrective action items?
A. No, I don't know why.
Q. And by the way, in referring to

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corporate, are they referring to corporate at MiniMed or corporate in Minneapolis?
A. Can't answer that question from here.
Q. When they use the shorthand corporate, do you know what they're referring to?
A. Corporate usually is referred to Minneapolis.
Q. Okay.
A. To Medtronic corporate.
Q. All right. Okay. And then the last step in the process flow was "Approve Plan." And that was assigned to the vice president of quality assurance, general manager of diabetes and SVP international, vice president quality assurance corporate.
What is SVP international --
A. Senior vice president.
Q. -- do you know?
Okay. Of international. And then vice president of quality assurance at corporate.
And you said you believe that refers typically to Minneapolis, Medtronic

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headquarters. Right?
A. Correct.
Q. All right. Let's skip ahead a number of pages, because a lot of this is redundant of an earlier one.
So if you could go to the page, the last three numbers are 192 down at the bottom right.
A. Which page, I'm sorry?
MS. MARTINEZ: 192.
THE WITNESS: I'm getting there.
BY MR. HAVERTY:
Q. It says "Next Steps."
A. One second, please.
Uh-huh, yes.
Q. Okay. And the next page after that is captioned "P-cap wet flow spec development."
Do you see that?
A. Yes.
Q. Could you tell us what that refers to?
A. This refers to development of a specification for the P-cap assembly that will

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govern, if you will, how much fluid -- to determine how much fluid can be deposited inside the P-cap while remaining functionality of the P-cap or the P-cap vent.
Q. Just --
A. The maximum amount of fluid allowed -- safely allowed that -- at which the P-cap membrane or P-cap venting properties will function as designed.
Q. Right. And so you actually did a study with people, did you not, that examined them misfilling the reservoirs and determining how much on average was deposited, the insulin. Correct?
A. That is correct. We did a study with 60 people who were given knowingly incorrect instructions on how to fill the reservoir, and then whenever spillage would occur, we would measure how much was spilled.
Q. And if you look to the next page, it's a slide that says, "How wet does the membrane get?"
Do you see that?
A. Yes.

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Q. And this dot plot, is this derived from the data from the study that you did with people who deliberately improperly filled the reservoirs?
A. Yes. Correct.
Q. And from that, you were trying to determine in actual practice what you might expect in terms of if someone makes this mistake, how much -- what's the maximum amount of insulin that could get spilled onto the reservoir and then contaminate the membrane. Right?
A. Correct.
Q. And from that, then you -- your goal was to develop a membrane material that could remain gas permeable even if the maximum amount of insulin was deposited on the reservoir and then contaminated the membrane. Correct?
A. Yes, but these studies were kind of independent.
Q. Well, but you needed some data points. Right? You needed to develop -- because the next thing that you developed was the wet flow specification. Correct?
A. Correct. So -- but it has not --

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it had nothing to do with the material selection. We needed to determine how much -- how much fluid can be produced during the incorrect -- incorrect filling of the reservoir and whether -- then whether our material can withstand that or not.
Q. Right. I thought that's what I -- maybe I said it incorrectly.
But the idea was you were collecting -- you needed to have a baseline of data for how much contamination are we talking about in the first place. Right?
A. Correct.
Q. Okay. And then if you go to the next slide -- and then we're going to break here -- but "Wet Flow vs. Applied Insulin," what does that mean? What's that referring to?
A. That means that there was a study done on I believe four materials at this point to determine -- to determine the correlation of a flow versus amount of, in this case, insulin deposited onto the membrane.
Q. Okay. And it's impossible to read that scatter plot.
But what does that tell you?

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What does the data mean just generally?
A. The first thing it tells us, that the membrane that was in production at that time gets saturated very quickly with very little and stops being permeable, and it also tells us that three materials -- at this point, we were down to three materials selected for further testing, that any of those three can fulfill the design requirement.
Q. And what was the -- meaning what, that it would still allow air to flow even when wet at -- maximally?
A. To -- to a certain point.
Q. Okay.
A. There is no membrane out there that can continue flow with -- with an infinite amount of fluid deposited.
Q. Right. And looking over to the right on the legend there, on this chart, it has the current membrane, then it has PM22S, Supor 450R and Versapor 450R. Right?
A. Correct.
Q. Okay. And there's three -- those other three, PMS -- PM22S, the Supor 450R, and

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the Versapor 450R, were the three remaining candidates of the original five that you developed. Correct?
A. Correct.
Q. And you may have told me, but I forgot, what was the reason that two of them were eliminated initially?
A. Due to the -- due to their physical -- physical properties, they were too brittle and too thin to handle in the machine environment.
Q. Okay. The PM22S, who is the manufacturer of that?
A. Porex.
Q. And the Supor 450R, who is the manufacturer of that?
A. Pall Corporation.
Q. P-A-L-L?
A. P-A-L-L.
Q. Okay. And the Versapor 450R, who is the manufacturer of that?
A. That is made by Pall as well.
Q. All right.
COURT REPORTER: Excuse me, by

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who?
MR. HAVERTY: Pall, Pall as well.
BY MR. HAVERTY:
Q. And how did you get to these suppliers of these materials? How did you select them?
A. So Ben Grover, who was a -- an engineer assigned to the project, he reached out, so, naturally, first to Pall Corporation, who is the manufacturer of the original membrane, if we can refer to that, the membrane that was used in the P-cap prior to change.
Q. That was --
A. And --
Q. Before you go there, that was the Emflon material. Right?
A. I think it called Emflon, yes.
MR. HAVERTY: E-M-F-L-O-N.
BY MR. HAVERTY:
Q. Yes. Okay.
A. It was only natural to reach out to a current supplier to seek help on this. And so two materials came from them.
And he also, through this

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research, found this company named Porex that specializes in filtration and membrane manufacturing.
Q. Okay. And if you go to the next page -- oh, I'm sorry. I interrupted you, and I meant to follow up.
The Versapor, how did you -- how did you get to them?
A. Both Versapor and Supor came from Pall Corporation, who were the supplier at the time.
Q. Okay. And then how did you get to Porex then?
A. Ben found them through his engineering research. I'm not sure how.
Q. Then the next page has "Blockages per 100 spills."
What's that referring to?
A. Okay. These I don't remember exactly. These are -- and it's hard to judge what these are from black-and-white graphs.
Q. Yeah, I know.
But if you look --
A. Yeah.

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Q. -- if you look to the legend, it has the various materials. And then in parentheses it has numbers, 0.21/100, 0.20 -- what is that referring to? Is that a quantitative analysis?
A. That's quantitative analysis and probably some projections, mathematical projections as to how many units will get blocked -- how many units of a sampled -- sample size of 100 will get blocked --
Q. Right.
A. -- when certain amount of fluid is introduced to them.
Q. Got it. So the PM22S was .21 out of 100 or 0.21 out of 100. The Supor was about the same, 0.20 out of 100. And the Versapor 450R was 0.14 out of 100. Right?
A. Correct.
Q. That was compared to the current Emflon membrane, which is 5.35 out of 100. Correct?
A. Correct.
Q. So that number is way in excess of the numbers for the other three materials.

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Correct?
A. Correct.
Q. And then if you go to the next page, it looks like it's essentially just a different version of the same data. Right?
A. Different -- different presentation of the same data, yeah.
Q. And then if you go to the next page, it has "Estimated Blockages per Million Spills."
Do you see that?
And it looks like it has ranges. Right?
A. Correct.
Q. So for the PM22S, the low was 2,132, and the high was 5,289.
The Supor was 2,020 for a low and 5,184 for a high.
And the Versapor 450R was 1,395 for a low and 4,425 for a high, as compared to the Emflon membrane, the current membrane, which was a low of 53,490 and a high of 63,227. Correct?
A. Correct.

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Q. So that's also, again, vastly in excess of the other three materials. Right?
A. That is correct.
Q. If you go to the next page real quickly, it says, "No Effect on FMEA." That's failure modes and effects analysis. Correct?
A. Yes.
Q. What is that referring to, are you able to tell?
A. Failure mode and effect analysis is an analytic tool that allows us to -- to predict and judge the potential risk of a certain failure.
Q. Right.
A. And also the occurrence and how well that potential failure can be detected and prevented.
Q. Right. And if you go to the bottom there, it's got the arrows talking about the vent membrane being blocked. Right?
And it says, the "Current Design Controls" for that is "Patient training" and "instructions for use." Correct?
A. Correct.

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Q. So what is this referring to? How does it -- when it says it has no effect on failure modes and effect analysis, what does that mean?
A. Because the introduction of a new membrane does not change the potential failure or potential for a failure. It may reduce the occurrence, but it does not completely prevent it from happening. So again, this is an analytical tool that assesses the potential of a failure and that stays present.
Q. And lastly, if you go to the next page, it says, "Based on current data Versapor 450R provides the greatest risk reduction for our customers."
Next bullet point, "No known membrane is capable of eliminating the risk."
Three, "We need to find a way to monitor the level of protection provided by the membrane going forward (wet flow spec?)"
Do you see that?
A. I do.
Q. Is that your recollection in the course of this CAPA about Versapor being the best

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candidate to reduce the risk of the blocked membrane?
MR. MERRELL: Objection -- objection to form.
THE WITNESS: At that point, yes.
BY MR. HAVERTY:
Q. Okay. And it talks about the wet flow spec. Again, we're going back to this.
Was that something -- we're going to talk about this after the break.
Is that something that you ultimately developed, because you said there is no known membrane cable of eliminating the risk, but you develop a spec that says that the -- must be gas permeable at a certain level depending upon an exposure to the contaminant --
A. Correct.
Q. -- that was what the wet flow spec was?
MR. HAVERTY: All right. Why don't we take a break here, and then we can pick up, and we'll talk about the development of the wet flow spec after the break. All right?

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MR. MERRELL: Okay.
MR. HAVERTY: Great.
THE VIDEOGRAPHER: We are now going off the record, and the time is 12:57 p.m.
- - -
(A luncheon recess was taken from 12:57 p.m. to 1:41 p.m.)
- - -
THE VIDEOGRAPHER: We are now going back on the record, and the time is 1:41 p.m.
BY MR. HAVERTY:
Q. Mr. Aleksandrovich, could you take a look at Exhibit 19, please.
- - -
(Deposition Exhibit No. AA-19, Field Corrective Action Plan - Paradigm Insulin Infusion Sets Potential for Fluid to Block Tubing Connector Vent Membranes DFCAP 2013-03 Rev 2 May 22, 2013, Bates stamped MDT-BRACP-029780 through MDT-BRACP-029809, was marked for identification.)

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- - -
MR. MERRELL: Corrective action plan. Okay.
BY MR. HAVERTY:
Q. You have it? Okay.
That's the field corrective action plan from May 22, 2013.
Do you see that?
A. Yes.
Q. Have you seen this field corrective action plan before?
A. I have.
Q. And by the way, let me go back to something I should have asked you way, way back at the beginning of this deposition.
What documents, if any, did you review in preparation for this deposition today?
A. So a copy of the CAPA report and whatever the attachments were to that and -- including this.
Q. Including the field --
A. This --
Q. -- the field corrective action?
A. The field corrective action

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report. And that's pretty much it.
Q. And when you said you reviewed the CAPA report, did you review the CAPA report that we've identified as Exhibit 2?
A. That is correct.
Q. That is the one that was -- that's the -- the last one, the one that was closed and should contain all of the synthesized information. Right?
A. Correct.
Q. Anyway, if you could turn to page -- it's the page at the bottom that's marked 29 -- the last three numbers are 784.
A. Okay.
Q. In the upper third of the field corrective action, it notes a potential health hazard relating to this blocked vent. It says, "The most significant hazard associated with tubing connector vent blocking is the potential for insulin over-delivery. This behavior could also result in temporary under-delivery of insulin.
"Although it is not clear whether or not the amount of insulin delivered will be

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less when the infusion set cannula is inserted into a patients subcutaneous tissue, the results of testing performed to date suggest there is a potential for significant insulin over-delivery if the tubing connector membranes are completely blocked. Significant insulin over-delivery can lead to death or serious injury if not treated immediately."
And that was consistent with the testing that was done and the root cause analysis and everything. Correct?
A. Correct.
Q. Okay. And by the way, were you consulted at all about this field corrective action?
A. No. In what aspect?
Q. In any aspect. Were you asked to offer any insights? Did you review it before it became final or --
A. No.
Q. All right.
A. No, I was not.
Q. The next paragraph goes -- says that "In addition there is also a risk of

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significant insulin under-delivery associated with blocked tubing connector vents. Preliminary testing suggests that if the infusion set is inserted after insulin stops flowing in situations where the tubing connector vents are blocked, insulin delivery will not resume immediately."
That's what we talked about earlier where there is a gap between the slide screw and the reservoir stopper. Correct?
A. Correct.
Q. Okay. And then underneath that, it says, "Distribution Information. As of the end of March 2013 a total of 428,000 current Paradigm insulin infusion pump users are registered in our database."
So that -- those would be the users actually, presumed users. Correct?
A. Correct.
Q. And then it notes the proposed field correction plan was to send communications "to inform patients to dry any spilled fluid that may come into contact with the inside of the tubing connector." So they were going to send

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out a customer letter, a healthcare professional letter, a distributor letter, a wholesale letter and "In addition to the communications provided to existing Paradigm pump users, a package insert...is being included with shipments of Paradigm insulin...reservoirs and Paradigm" insulin "infusion sets."

Do you see that?

A. I do.

Q. And do you know what the package insert was that was attached to it?

A. No. I do not recall this. This package insert is utilized in our warehouse in Kentucky, and I don't think I've ever seen that insert.

Q. Okay. And by the way, am I correct, to short-circuit this a little bit, but ultimately the FDA characterized this corrective action as a Class 1 recall, did it not?

A. That is correct.

Q. And the reason for that was because of the severity of the risk. Correct?

A. I can't speak to FDA's reasons.

Q. But you know that they

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specifically identified it as a Class 1 recall. Right?

A. That I do, yes.

Q. Okay. And if you turn to the page numbered 793. This is patient --

A. Go ahead.

Q. This is an "Urgent Medical Device Safety Notification" relating to the "Potential for Over or Under Delivery of Insulin if Insulin or Other Fluids Contact the Inside of Medtronic Paradigm Infusion Set Connectors."

Do you see that?

A. Yes.

Q. This was the letter that was sent to patients in early June of 2013, is it not?

A. I'm not sure when it was sent to patients, but yes, it is a letter that was sent to patients.

Q. And in it here, there's a pictograph with some text that shows how to properly disconnect the reservoir -- the reservoir from the transfer guard. Correct?

A. Correct.

Q. And this was sent in the manner

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of, as we talked about a little bit earlier, a form of warning to the patients to instruct them how to avoid getting the insulin spilled on the reservoir top. Correct?

A. Yes. Correct.

Q. So this was one of the corrective actions in the corrective and preventative action program. Correct?

MR. MERRELL: Objection to form.

THE WITNESS: Again, I wouldn't bucketize these actions that we take as part of CAPA to -- into corrective and preventative. This -- the entire goal of the CAPA is to provide a solution to keep the patient safe.

BY MR. HAVERTY:

Q. Right. But this was a -- this was a near-term solution, because you didn't know how long it was going to take or if you even could design out the hazard that you had identified. Correct?

A. That is --

MR. MERRELL: Objection to form.

THE WITNESS: That is correct.

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It was an immediate solution, yes.

BY MR. HAVERTY:

Q. But I think you told us a little bit earlier that the people who were involved in the CAPA did not think it was a satisfactory solution because of the possibility of the human error leading to this over-delivery of insulin. Correct?

MR. MERRELL: Objection to form.

THE WITNESS: That is correct. We wanted to -- to ensure that we take even the possibility of this thing happening away from patient as much as we can.

BY MR. HAVERTY:

Q. If you could go back to Exhibit 10, please.

- - -

(A discussion off the record occurred.)

- - -

BY MR. HAVERTY:

Q. Yeah, and I think -- and actually, I will represent to you I think that

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these are -- were intended to be two separate exhibits, but they got mashed together for some reason. So the numbering may be a little bit confusing.

But, you know, let me ask you, if you could go to the page marked 242. It's near the back. It's about ten pages from the end or so.

A. 242.

Q. 242?

MS. MARTINEZ: NO.

THE WITNESS: 0069242 (sic).

Right?

BY MR. HAVERTY:

Q. Yeah. But I said, there are actually two things together. The numbering is not in sequence, so go all the way towards the end first.

MR. MERRELL: 0067242.

MS. MARTINEZ: Oh.

MR. HAVERTY: Yeah.

THE WITNESS: 7247. I'm lost.

MR. MERRELL: It's not in sequence.

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THE WITNESS: Oh, there we go. 7242. Yes.

BY MR. HAVERTY:

Q. Got it. Okay. And it's a slide deck called "Prime/Fill Anomaly - Paradigm CAPA"?

A. Correct.

Q. And it's from Juan Alderete? Yeah. It's dated July 5, 2013?

A. Uh-huh.

Q. Right?

A. Yes. That's it.

Q. Have you -- if you just take a quick look at this, have you seen this slide deck before?

A. I don't remember exactly.

Q. Who is Juan Alderete?

A. He is an R&D engineer at Medtronic.

Q. Was he part of the CAPA team?

A. No, he was not.

Q. Do you know why he was giving a presentation on the "Prime/Fill Anomaly - Paradigm CAPA"?

A. No, I don't remember exactly why.

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Q. Would you -- do you recall whether you were involved in any type of presentation in July of 2013 regarding the Paradigm CAPA?

A. July 2013 -- could you please ask me that question again?

Q. Sure. Let me make it a little bit easier for you.

A. Uh-huh.

Q. Let me do it this way.

Hold that page open and go to Exhibit 17, if you would.

- - -

(Deposition Exhibit No. AA-17, Meeting Invitation, 6/3/2013, Bates stamped MDT-BRACP-0054646, was marked for identification.)

- - -

THE WITNESS: Okay.

BY MR. HAVERTY:

Q. Do you have that?

A. Yes.

Q. This is an email from Juan Alderete to, among other people, you, Benjamin

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Grover and Mark Curtis.

These are part of your CAPA team. Correct?

A. Some people are. Some are just R&D people.

Q. Yeah. No, no. But the ones that I identified, Benjamin Grover, Mark Curtis, you, they were all -- you were part of that CAPA team. Right?

A. Correct.

Q. And I also note, there is another person in there, Afshin Bazargan.

Who is Afshin Bazargan?

A. He's an R&D director --

Q. Okay. Is he still with Medtronic?

A. -- at Medtronic.

Q. Is he still with Medtronic?

A. He is.

Q. Okay. Anyway, this -- it looks like this was a meeting invitation for a meeting for "Concept Generation for Venting Reservoir" Component -- "Compartment" for June 3rd of 2013.

Do you recall going to such a

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meeting?
A. Yes, I do.
Q. Okay. What was the purpose of the meeting?
A. To potentially generate a hardware solutions to prevent -- or to provide venting through the pump or some other means of venting the reservoir compartment.
Q. Okay. All right. So if you go back to Exhibit 10, that page we were on, and you go to 243, which is the next page after that, it says, "Project Charter," and it has a "Problem Statement, The P-Cap membrane can become occluded and effect the pressure equalization of the System." That's identified as the "Issue Statement."
Then it says, "Through Design, our tube based systems should equalize the reservoir compartment pressure under typical use conditions," and that's "Vision."
And "We will use the DMAIC process to evaluate potential design solutions in order to reduce/mitigate the risk." And that's identified as the "Method."

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Can you tell us what these things are, the Statement, the Vision and the Method, what does that refer to?
A. This was a project -- conceptual project to try to generate some of the solutions via hardware to provide venting to the reservoir compartment.
Q. Or -- or otherwise prevent the hazard from occurring. Right? Even it was not necessarily through venting. Right?
A. Well, I wouldn't agree with that. It's all about venting. It's all about letting air out of the compartment.
Q. Okay. We'll get to that in a second.
Anyway, in any event, it notes that the "Project Goal" was to "Perform root cause analysis to determine failure modes and propose solutions to reduce/mitigate the failures." Right?
A. Yes.
Q. And do you recall -- you recall this project at all? Were you involved in this project?

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A. I participated in a couple of meetings and, like I said, idea generations.
Q. Okay. And then the "Project Scope" involves the Paradigm/NGP infusion sets and reservoirs, the 1.8 and 3.0 milliliter and the Paradigm/NGP pumps 5X -- 5 series and the 7 series. Correct?
A. Correct.
Q. And, by the way, all of the stuff that we've been talking about, there are two models of pump back in this time. There was the 5 series and the 7 series. Correct?
A. Correct.
Q. The only difference between the 5 series and the 7 series was the size of the reservoirs. Correct?
A. Correct. And the size of the pump itself. Yeah.
Q. But all of the issues that we're talking about with the blocked vents and all that, they apply equally to the 7 series as they do to the 5 series. Correct?
A. Correct. It's pump independent. Yes.

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Q. Okay. Anyway, if you go ahead to the page marked 252, okay, this looks like some conceptual discussions about different ways of mitigating the risk, does it not?
A. Am I looking at the proper slide, "Improved Membrane (Hydrophobic on both sides)"?
Q. Yes. As a matter of fact --
A. Okay.
Q. Right. If you look at the next five pages or so, or four pages, after that, do these look all like conceptual -- concepts for how to mitigate the risk from the venting being blocked?
A. Yes. That's what they look like.
Q. Okay. So the first one is "Improved Membrane (Hydrophobic on both sides)." And then it looks to me like it talks about the benefits and -- or the pluses and the minuses of each approach.
And in this case, the plus of it was that it "Mitigates the membrane from becoming obstructed," but the -- it looks like the con would be "Development would be heavy on process and automation."

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What does that mean?
A. That means that what we talked about earlier then, big concern with -- in selecting the new material was how was it going to act in the high-volume manufacturing environment being used in our automated assembly systems.
Q. And then it says, "Proof of Concept demonstrated acceptable Wet Flow Capability."
And was that what we talked about before the break, where you had these three materials that all performed vastly better than the Emflon material?
A. Right. This basically demonstrated that there are materials on the market that can withstand a certain amount of fluid and remain permeable.
Q. Okay. If you turn to the next page, please.
A. Yes.
Q. Is this another concept that was discussed, "Reservoir to Electronics Chamber Venting"?

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A. Yes.
Q. Can you explain what that concept was?
A. I don't remember exactly, but the idea was to vent the reservoir compartment, instead of venting it to the atmosphere or environment, as is done currently, to implement some kind of valve that would let the air go inside the -- essentially housing of the pump.
Q. Okay. So it notes that the pros are that it "Mitigates the over-pressurization of the Reservoir Compartment." And it says, "Small reservoir frictions retire large volume to prevent stopper movement."
What does that mean?
A. "Small reservoir frictions" -- I'm not sure what it means.
Q. Okay. And then the next point under it is, "End result is that reservoir could empty before seating is triggered (no over-delivery). Pump would seat with stopper bottomed out and would be followed by a Low Reservoir Alert."
Do you -- can you explain how

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that was supposed to work?
A. It basically means that in the event where uncontrolled delivery would happen, it would empty into -- no, I'm sorry. Strike that. I'm wrong. No, I don't remember this concept. Uh-uh.
Q. Okay. And the next bullet point is "Reliability Testing needed to determine performance over 4 years."
Is that relating to the life of the -- the life expectancy of the pump?
A. Yes, that is correct.
Q. So that would have a long lead time in order to validate it and test that particular methodology. Correct?
A. That is correct.
Q. And I assume that was considered to be a major con for this work-around. Right?
A. Yes.
Q. All right. But then it noted the "Proof of Concept demonstrated acceptable capabilities with obstructed membrane."
How is a proof of concept done for that particular methodology?

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A. I cannot speculate on this, because I have not seen that proof of concept.
Q. Okay. If you go to the next page, please, this one is titled "Reservoir Removal Prevention Feature." Okay.
Basically this would prevent the user from making that error of removing the reservoir while it's underneath a pressurized insulin vial. Correct?
A. Correct.
Q. And it notes that the major pro for this is that it "Mitigates the root cause (insulin getting on membrane): locks Reservoir while the Vial is attached."
Then it says, it "Only impacts the Transfer Guard Tooling."
So that would have been a major plus as well, because it sounds like you wouldn't have had to do a whole major redesign of the transfer guard. Right?
MR. MERRELL: Objection to form.
THE WITNESS: Well, it's still a major redesign considering the tooling we use.

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BY MR. HAVERTY:
Q. Okay. But --
A. And -- yeah. Still is.
Q. And the con that was noted there is "Would not prevent the membrane from getting wetted in other typical use cases." Right?
A. Uh-huh, yes.
Q. What were the other -- what were the other typical use cases that were foreseen that could lead to the wetting of the membrane other than detaching it -- detaching the reservoir from the transfer guard while it was underneath a pressurized insulin vial?
A. Again, hard to answer at this point. I don't remember. But one was doing this within -- within short distance of water source, running faucet, shower, something like that.
Q. Okay. Was this, the reservoir removal prevention feature, ever explored any further than this apparent conceptual slide, do you know?
A. Not to my knowledge.
Q. Was there anybody who advocated for it, that thought that it was a viable

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possible risk mitigation?
A. Don't remember.
Q. Okay. And then if you turn to the next page, please. This looks like it's another concept, "Detection of Increasing Pressure." And it says, "Detection of whether the force increase during seating is caused by contacting the stopper or compression of air. Development would be heavy on testing and aging of devices." And "Review of preliminary data demonstrates a capability to develop an algorithm for both Paradigm and NGP.
By the way, what is NGP?
A. It's an abbreviation for new generation pump.
Q. All right. Can you -- and as best you can, explain it to people who are not engineers, can you explain what this concept is discussing?
A. To the best of my knowledge, this was a software approach to -- to embed into the pumps software that will detect -- it will be able to tell the difference between when it's -- when the occlusion is caused -- or when it's

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seating -- when actual seating occurs versus air incursion.
Q. And that's because actual seating occurs when the slide screw detects a certain level of pressure. Right? And then it stops. Correct?
A. That was the idea.
Q. Do you know what were the major -- what was a -- the negative about this concept, if you know?
A. No, I don't.
Q. Okay. Do you know whether that was explored any further than this concept here?
A. I'm not aware, no.
Q. Do you know whether those work-arounds were actually rejected, or were they just -- they just were never pursued any further?
A. I don't think -- yeah. I don't remember how -- how we stopped those -- that development. But yeah, to my knowledge, they were not pursued any further.
Q. Okay. If you could look at Exhibit 22, please.
- - -

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(Deposition Exhibit No. AA-22, Engineering Reports, ER13-8302 Version A, 06/28/2013, Bates stamped MDT-BRACP-029066 through MDT-BRACP-029082, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. Do you have that?
A. Yes.
Q. Okay. And this is an engineering report that you prepared at the end of June of 2013. Correct? And it basically was a synopsis --
A. Looks like it.
Q. I'm sorry.
A. Yes.
Q. Okay. And it basically is a synopsis of the events that occurred from the original complaint back in the fall of 2012 through the investigation, the engineering investigation and the other analyses that were done. Correct?
A. Correct.

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Q. So this would be a good -- a good summary of all the events that occurred up through the end of June 2013. Right?
A. Right.
Q. Okay. And actually, it contains most of the events that we discussed already. Correct?
A. That is correct.
Q. All right. If you could take a look at Exhibit 23, please.
- - -
(Deposition Exhibit No. AA-23, Memo dated July 31, 2013, Bates stamped MDT-BRACP-0051047 through MDT-BRACP-0051050, was marked for identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. Do you have that?
A. I do.
Q. Okay. Do you see this appears to be a summary of meeting minutes between representatives from Medtronic and the FDA, July

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31st of 2013. It was held at the FDA Office of Compliance.
You're not listed as an attendee, but did you ever interact with the FDA over any of the issues relating to the prime/fill anomaly CAPA?
A. No, I never did.
Q. Did you ever provide any information to anybody at Medtronic who was then interacting with the FDA regarding issues surrounding the prime/fill anomaly?
A. Yes.
Q. Okay. Who did you provide information to?
A. Norma Ojeda.
Q. She's listed as one of the attendees here. Correct?
A. Correct.
Q. And she's listed as a senior engineering manager.
Was she your supervisor?
A. Correct. She was at the time.
Q. Okay. Is she no longer with Medtronic?

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A. She's still with Medtronic in a different capacity.
Q. Okay. What is she doing now?
A. She is a senior quality director.
Q. Okay. And it looks like it lists five meeting action items.
And it's -- it was "Medtronic to advise FDA on the decision related to the updated keypad and the installed base of 510(k) pumps. With a further discussion on the issue of how to incorporate improvements into all pumps in the marketplace."
Do you know anything about what that discussion was about?
A. No, I don't.
Q. Do you know what it's referring to as "the installed base of 510(k) pumps"?
A. No, I don't.
Q. Do you know what a 510(k) pump is?
A. No, I don't.
Q. Do you know what the 510(k) process is? Do you know what that refers to?
A. I do know what it refers to. I'm

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not sure how the process actually works.
Q. Okay. Well, what does it -- what does it refer to? What's your understanding of it? What's the 510(k) referring to there?
A. It's a -- it's a type of submission that FDA would require in certain new products or changes or whatever else happens in our business. It's an FDA submission, a type of.
Q. And in fact -- and we're going to get to this in a little while, but there was a 510(k) submission related to the new membrane material for the P-cap connector. Right?
A. That is correct.
Q. All right. Then the second one is "Medtronic Diabetes to inform FDA related to the effectiveness of product update cards in disposable shipments."
Do you know what that's referring to?
A. No, I don't.
Q. Do you know what the product update cards are?
A. Not really, no.
Q. Medtronic -- third item,

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"Medtronic Diabetes to share with FDA how we get information related to product updates to physicians who do not receive product."
Do you know what that's referring to?
A. Nope.
Q. Okay. Fourth item, "Medtronic to update procedure to include completed Health Hazard Assessments in 806 notifications to" the "FDA."
Do you know what that's referring to?
A. No, I don't.
Q. Do you know what 806 notifications are?
A. No, I don't.
Q. Okay. Do you know anything about medical device reporting?
A. No, nothing specific.
Q. Okay. Then Item 5, "Medtronic to update field communication matrix and schedule a follow up meeting discussing the risk definitions and frequency levels with" the "FDA."
Do you see that? Do know what

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that's referring to?
A. No, I don't.
Q. Okay. All right. In any event, if you turn to the next page, please. It lists a number of issues that were discussed, apparently were discussed at this meeting, the first being the "Keypad Improvement slide."
Do you know what that's referring to?
A. No.
Q. Then the second one is "Motor Error Phase II slide."
Do you know what that is referring to?
A. No, I don't.
Q. Do you know what the motor error is dealing with?
A. No.
Q. Do you know -- and if you look at the next one, "Motor Support Disc," do you know what that's referring to?
A. Nope, I don't.
Q. The next one is "Moisture Ingress."

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Do you know what that's referring to?
A. No, I actually don't.
Q. All right.
A. Not in this context.
Q. Okay.
A. Not in this context.
Q. The next one, "Field Corrective Action-Motor support disc," do you know what issues were surrounding the motor support disc?
A. Not really.
Q. Then the next one, turn to the next page, if you would. It has the "Field Corrective Action-Vent Block."
You do know about that. Right?
A. I do.
Q. And then it goes on to say, "John Diehl and Carl Fischer asked if a health hazard assessment was done and if so was it provided?"
We know that a health hazard assessment was done. Correct?
A. It was done. I don't know a time reference between this and -- when this meeting occurred and when the HHA was done for this

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particular case.
Q. Okay. We saw that the health hazard evaluation was done in the spring of 2013. Right?
A. I don't remember from the documents.
Q. And then it says, "Mr. Fischer further clarified that going forward whenever Medtronic Diabetes submits an 806, FDA would appreciate if you would provide a health hazard assessment."
Do you know what that's referring to?
A. No.
Q. And then the next bullet point, it says, "Dr. Beaston inquired if Medtronic Diabetes is planning a better correction than just telling patients what to avoid?"
Were you aware of that, that the FDA was interested in whether or not FDA -- Medtronic was going to do more than simply send out the "dear healthcare provider" letters or the "dear patient" letters?
A. No, I'm not aware of the

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communication.
Q. Okay. But then Jeff Hubauer -- who is Jeff Hubauer?
A. Jeff Hubauer was -- I don't know at the time, vice president of Medtronic Diabetes.
Q. All right. He informed the FDA people "that design changes are being evaluated and that we expect to go to new vent membrane to eliminate this issue."
So that was the thinking -- that was Medtronic's approach at that time. Correct?
A. Yes.
Q. Okay. If you could look at Exhibit 24, please.
- - -
(Deposition Exhibit No. AA-24, Email chain, top one dated August 08, 2013, Bates stamped MDT-BRACP-0067708 and MDT-BRACP-0067709, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. Do you have that?

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A. I do.
Q. Okay. Who is Amichai Vardi?
A. Amichai Vardi was a quality director at that time.
Q. Okay. And the second email on this chain is from Amichai Vardi to a number of people, including you, dated August 6, 2013. Correct?
A. Uh-huh. Correct.
Q. And at this point, in August of 2013, had you -- had you made a decision to go ahead and explore the Versapor 450 more fully at that point?
A. I don't remember. I need to refer to the -- to our engineering report documentation.
Q. Of the engineering -- your engineering report from the end of June?
A. No, no, not my engineering report. It's from Benjamin Grover, the report that -- where he compares the materials.
Q. Okay. But do you recall around when that was -- is that that slide deck we were talking about?

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A. That slide probably led to that report. I don't exactly remember when we released that.
Q. Okay. Beyond doing the blocked vent testing, and you found that Versapor was the best risk mitigator of all the materials tested, did you then -- or what did you do next at that point?
MR. MERRELL: Objection to form.
THE WITNESS: Are you asking me what were the steps we took after identifying Versapor 450 as a replacement material? Did I understand you correctly?
BY MR. HAVERTY:
Q. Yes. I mean, when did you make the decision to pursue Versapor as your basic solution?
A. Upon completion -- upon completion of the comparison testing for three materials.
Q. We talked --
A. It was basically -- yes. Correct. It was determined that any of those

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three will be a good candidate as a replacement, but we choose Versapor 450.
Q. Okay. And that was a product that was made by Pall, who was the current manufacturer -- or current supplier of the Emflon material that was currently in the P-caps. Right?
A. Correct, yes.
Q. So what was the next step then once you settled on Versapor as your material of choice? What did you do next?
A. Next high-level step was to see how it would act in the -- in the assembly machine and then subsequently validate it.
Q. Okay. How did you go about that process? You had to obtain --
A. We created a -- we created a part number specific to the form that we needed to receive that material in, and then we commenced or commissioned our supplier to -- that possessed one of the cap assembly -- we refer to them as cap assembly machines, the assembly cells that assembled P-caps, to create and develop a process for the Versapor 450 with a subsequent ID to go

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into validation.
Q. Okay. How, if at all, did the manufacturer of the membrane with the Versapor on this CAM machine differ from the Emflon?
A. I'm sorry. I'm not clear on the question.
Q. Yeah. I probably need to lay a better foundation.
So was the idea that you're going to use the Versapor as a single-membrane material, or were you going to use the Versapor in combination with the hydrophobic PTFE that was already in the membrane?
A. No. Versapor 450 is a material of its own that is hydrophobic and would provide enough -- enough protection that we were looking for.
Q. So you're only going now with a single-layer membrane. Right?
A. It's single material of membrane. I don't remember -- I don't think Versapor is constructed with a single layer of material. But it's a material as the supplier makes it.
Q. Let me go back then.

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Because what you would have to do with the Emflon membrane was you had to weld or you had to join the polyester and the PTFE, correct, as part of the manufacturing process?
A. This is proprietary to Pall -- to Pall corporation. I have no idea how they -- in fact, we wanted to see how they manufactured it, and they wouldn't allow us.
Q. So just so I understand, the material came to you already as a two-layer -- the PTFE and the woven -- nonwoven polyester from Pall. Correct?
A. Correct.
Q. And that's what I'm trying to understand. The Versapor then, whatever component -- constituent parts it has in it, came to you from Pall as a finished product, a finished membrane. Correct?
A. Correct. The only customization of that material will be -- would be the width to which it was slit to fit the machine.
Q. Okay. And that's what I was trying to understand.
So you needed to validate or test

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the materials on the machine to determine what width you needed Pall to manufacture it to?
A. No. We -- we knew the -- the width never changed from Emflon to Versapor 450. What we needed to do is to develop -- so the membrane material is welded via ultrasonic welding process to the plastic housing. We needed to develop a new --
Q. I'm sorry, what --
A. And we needed to develop a new --
Q. I missed the last part of that.
A. I'm sorry.
Q. My fault.
A. We needed to develop a new welding process for the new material, because the old process wouldn't work for it.
Q. And how did the old process not work? What was the problem?
A. It would burn holes in the new material, as one of the examples.
Q. Anything else?
A. Not at that point.
Q. Okay. So sometime in the spring or early summer of 2013, you settled on the

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Versapor, and you attempted to get materials from Pall so that you could test it out on the -- on your manufacturing equipment and figure out how it would work with the CAM machines. Correct?
A. Correct.
Q. So do you recall the period of time when that type of validation was going on in terms of the sonic welding and whatever else you needed to do to get that membrane into the cap?
A. No. I don't remember the exact time frame when that was happening.
Q. But was that going on during the summer and the fall of 2013?
A. Again, I don't remember. It's all documented in our reports, but I don't remember exactly off the top of my head right now.
Q. Okay. If you could look at Exhibit 25, please.
- - -
(Deposition Exhibit No. AA-25, Engineering Change Form, ECR/ECO: 5-46903, Bates stamped MDT-BRACP-0062972 through MDT-BRACP-0062976, was marked for

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identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. This is an Engineering Change Form dated 9/18/2013. And it notes that the summary of the change is "FDA required update to infusion set artwork to add caution and warnings regarding blocked vents issue. Release prototype and production versions of artwork required to ensure patient safety." And it says the "Reason For Change, FDA required update for patient safety."
And then it says, "Qualifying/Validation, No new claims. Changes are required per FDA to ensure patient safety and warnings about potential harm if blocked vents occur."
Do you see that?
A. Yes, I do.
Q. Do you recall what those instructions were, what the warnings were?
A. Yes.
Q. What were they?

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A. This -- we were -- within this change form, we were adding to the warnings section of every IFU of an infusion set. We were adding a wording against presence of insulin or any other fluid. I don't remember the exact verbiage, but that's the essence.
Q. Okay. If you could, please, look at Exhibit 26.
- - -
(Deposition Exhibit No. AA-26, MiniMed Reservoir Instructions for Use, Bates stamped MDT-BRACP-028899 and MDT-BRACP-028900, was marked for identification.)
- - -
THE WITNESS: Go ahead.
BY MR. HAVERTY:
Q. You have it. Okay.
If you could go to the second page of that.
A. Okay.
Q. All right. Up at the top left, like first column -- second column over, do you see there's a thing in English? Do you see that?

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A. Yes.
Q. It starts off with -- it starts off with "Indications For Use."
A. Yes.
Q. Right? And then underneath that, it says "Warnings." Right?
A. Yes.
Q. And if you go over to the next column, on the second paragraph, it says, "If insulin, or any liquid," gels -- excuse me -- "gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the delivery of too" much -- "too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set."
Is that the updated warning that you recall the FDA required?
A. That is.
Q. And if you go over to the first column there, the very top of it, it says on there, "Refer to pump and infusion set user

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guides for installation and filling."
Do you see that?
A. Yes.
Q. Do you recall whether that was a new instruction on this information for users?
A. No, I don't recall.
Q. By the way, just so we're clear for the record, this Exhibit 26 is the IFU for the MiniMed reservoirs. Correct?
A. Correct.
Q. And the IFUs are the documents that accompany the disposables in the boxes in which they're shipped to consumers. Correct?
A. Correct.
Q. If you then could look at Exhibit 27, please.
- - -
(Deposition Exhibit No. AA-27, Medtronic Quick-set Instructions for Use, Bates stamped MDT-BRACP-028901 and MDT-BRACP-028902, was marked for identification.)
- - -
BY MR. HAVERTY:

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Q. And this is the IFU for the Medtronic Quick-set infusion sets. Correct?
A. Correct. One of them, yes.
Q. And if you look at the -- underneath the Medtronic logo, there is a -- in that black-lined box there, there is the first thing, it says, "Refer to pump and reservoir user guides for installation and priming."
Do you see that?
A. Yes, I do.
Q. Okay. Do you know whether that was new information, a change in these labels?
A. I don't remember if it was new information.
Q. Okay. And if you look at the pictograph number 3, do you see that?
A. Yes, I do.
Q. It looks like it has two connectors depicted there. One on the left top part, it appears to be a P-cap being connected to a reservoir.
Do you see that?
A. Yes.
Q. And in the one to the right, in

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the lower portion of it, it looks like a different type of connector onto the reservoir, does it not?
A. Correct. It does.
Q. Is that -- is that a Luer Lock connector?
A. It is a Luer Lock connector, yes.
Q. So are you able to tell what type of reservoir that is that's being depicted there that can be used with a Luer Lock connector?
A. There's only one reservoir that Medtronic manufactures that can be connected to a Luer Lock connector.
Q. And what was that?
A. I don't remember the model number.
Q. Well, would that reservoir work in a MiniMed pump?
A. No, it wouldn't.
Q. Okay. What pumps would it -- would it only work in?
A. Whichever pumps by other manufactures that can utilize such reservoir.
Q. Well, this is -- this is an IFU

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for the Quick-sets, so why is it depicting a Luer Lock in addition to a P-cap connector, if you know?
A. Because -- because Medtronic markets Quick-set infusion sets with both connectors.
Q. And by the way, the Luer Lock connector wouldn't suffer from the same problem as the proprietary connector because it doesn't rely upon venting. Correct?
A. Correct. It's completely different physics, yes.
Q. Was there any consideration given to developing a Luer Lock connector for the reservoirs that would not have the venting problem that the P-cap had?
A. Not that I remember.
Q. Do you remember any discussion about it at all?
A. I don't.
Q. If you could turn to the second page, please.
A. Okay.
Q. All right. If you go down --

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never mind.
If you can go to Exhibit 28, please.
- - -
(Deposition Exhibit No. AA-28, Medtronic MiniMed Paradigm Reservoir Instructions for Use, Bates stamped MDT-BRACP-028897 and MDT-BRACP-028898, was marked for identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. All right. You recognize this as an IFU for MiniMed reservoirs?
A. Okay.
Q. Do you recognize this as the IFU that was in use prior to the discovery of the prime/fill anomaly or the temporary vent block?
A. I am not sure which one was used when in reference to reservoirs.
Q. Okay. If you could take a look at page 2.
A. Okay.
Q. Do you agree with me that the

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warning that was in -- I guess it was Exhibit 26, about insulin or anything getting on the reservoir top is not contained in this reservoir IFU?
A. I would agree, yes.
Q. Okay. And in fact, at the bottom there, after pictograph number 10 to the right of that, it says differently than the one in Exhibit 26, "Refer to Paradigm Pump User Guide for inserting reservoir, priming pump, and inserting infusion set." Correct?
A. Correct.
Q. The new -- newer warning, the updated warning, referred the user to the user guide for the filling instructions as well. Correct? If you want to take a look at it.
A. Yes.
Q. If you could take a look at Exhibit 30, please.
- - -
(Deposition Exhibit No. AA-30, PowerPoint, "Temporary Vent Block During Prime CAPA (QIT13-006)," Bates stamped MDT-BRACP-0054462 through

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MDT-BRACP-0054469, was marked for identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. This is a PowerPoint slide deck titled "Temporary Vent Block During Prime CAPA... Project Summary," and it's got your name on it, from December 12, 2013. Correct?
A. Yes.
Q. And I take it from that, this was a presentation that you made to explain where you were in the CAPA process as of the end of 2013. Correct?
A. Correct.
Q. If you could look at second page of this.
A. Okay.
Q. What is that graph meant to depict?
A. This graph shows the testing of historical samples of hardware that we could obtain that we spoke about earlier today.
Q. Okay. And that's where you refer

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to, somewhere in 2009 we lost the ability to pass air through the membranes. Correct?
A. Yeah. Actually, even earlier than then.
Q. Where does it appear on this graph?
A. I think it has a stamp -- it's very blurry here, but I think it has a stamp of 2000 -- October of 2008.
Q. Okay. And the top line graph, what is that depicting? What is that referring to?
A. That's air flow through the membrane in the dry condition.
Q. Okay. So as it goes off to the right -- and then it goes way up to 80 -- what's -- SCCM and above that, what is that -- is that saying that's good air flow in the dry membrane?
A. That's very good air flow, yes.
Q. Okay. And then the one that's underneath of it reflects the air flow through a wet membrane. Correct?
A. Correct.

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Q. And what it shows is that at some point, it was as high as 22 or so. And then it dropped to under 10 and continued on its way down to where it got to basically 0. Correct?
A. Correct.
Q. If you turn to the next page, please.
A. Okay.
Q. And what is this slide meant to depict?
A. This shows -- this shows how we utilize -- how the team utilized a tool cause -- called root cause investigation analysis or root cause analysis to determine potential causes of an issue and to kind of evaluate them as to which are more probable or more important to go after and separate them from the ones that we deemed insignificant at that point.
Q. Okay. So what does this tell you about what the root causes were and what things were most significant?
A. So it tells -- tells us that the most significant were the membrane material itself, the CAM machine, as in what could CAM

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machine -- could it have altered the material in any shape or form during manufacturing to create such condition.
Q. Right.
A. And then the weld horn design, that's going into more details within CAM machine. Weld horn is not -- weld horn is a tool -- one of the tools that is used inside the CAM machine to attach the membrane to the plastic P-cap housing.
Q. Okay. And were you ultimately able to determine whether the CAM was responsible or the weld horn design was responsible?
A. No. We eventually ruled both of those out.
Q. So it got down to the point where you realized it was purely a function of the membrane material. Right?
A. Correct. Yes.
Q. All right. If you go to the next slide, please.
A. Okay.
Q. You've got -- you described the problem, the membrane becomes gas impermeable

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when liquid is deposited on it and how that happens.
And then you note that "Membrane material needs to be replaced with material that will remain gas permeable when temporary wet." Right?
A. Right.
Q. And that was at that point, at least as of the end of 2013, that was the direction that the CAPA was headed. Correct?
A. Correct.
Q. And then you note that the "Amount of liquid permitted on membrane needs to be determined." Right?
A. Correct.
Q. And that ultimately became the wet flow spec. Right?
A. That is correct.
Q. If you turn to the next slide, please.
That's the "'Wet' Spec Development." We talked about that earlier. This is determining how much insulin would get deposited if somebody followed an improper

Page 216

filling technique. Correct?
A. That is correct.
Q. If you turn to the next page then.
So you talk about the "Material, 5 potential materials identified (3 from current supplier and 2 from a potentially new supplier)."
You eliminated two of those. Correct?
A. Correct.
Q. Well, you noted "PCAP assembly samples built using 5 prospective materials and 3 times sterilized." And then "Preliminary testing eliminated 2 materials."
What was the preliminary testing that was done that eliminated two of the materials?
A. If I remember correctly, both wet and -- wet -- dry and wet flow.
Q. Okay. The wet flow was unacceptable?
A. I don't remember exactly the cause that we eliminated for the first two

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materials, but yeah. One of them was a wet flow. Wet flow unacceptable or inconsistent.
Q. Okay. If you turn to the next page, please.
You note "New Material Selection." The "3 Remaining materials underwent array of functional testing."
And "Per results of preliminary testing all 3 materials are promising for production." Correct?
A. Correct.
Q. So then if you turn to the next slide, as of December of 2013, your plan was to finalize the reports for the mechanical testing and wet flow spec development. And then Develop and document specification for wet flow. Create part numbers for all 3 materials. Procure 'validation' quantity of all 3 materials. And Develop preliminary welding process window. Develop a validation plan and schedule. Right?
A. Right.
Q. And so based upon this report in December of 2013, were you pretty much on schedule with the projected schedule that we

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discussed from the CAPA report?
A. I don't remember. I need to refer back to the schedule.
Q. Okay. You were -- the original plan from Exhibit 2 on page 42 said that you were getting -- you expected to identify alternative materials as of October 15, 2013.
So you were on schedule with that. Right?
A. We were on schedule for that, yes.
Q. And then -- I'm sorry. I was looking at the wrong page. Page 8, by the way.
MS. MARTINEZ: Of what exhibit?
THE WITNESS: Number 2.
MR. HAVERTY: Page 8.
THE WITNESS: I lost it. Sorry.
One second. Right here.
BY MR. HAVERTY:
Q. Yeah.
A. Here, page 8. I got it.
Q. Okay. As of December of 2013, were you on schedule to validate the assembly process using new material?

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A. Yes.
Q. And let me qualify that a little bit.
If you look back at page 42 as well, is this a more updated action plan because -- I mean, sorry.
Was this the original action plan from August of 2013?
And the reason I ask is because number 2, "Validate Assembly Process Using New Material" had a due date at that point as of February 14, 2014.
Did that get moved? Did that get pushed up?
A. It may have been.
Q. Okay. Do you know why it was moved from February of 2004 to May of 2004? Or '14, excuse me.
A. Probably we -- no. I don't remember exactly why it got moved.
Q. Okay. And then because the design review on page 8 was due on 4/24/2014, and it looks like the original schedule was for that to be in February of 2014?

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A. Okay.
Q. Do you know why that was pushed back?
A. No. I don't remember why.
Q. All right. If you could look at Exhibit 32, please.
- - -
(Deposition Exhibit No. AA-32, PowerPoint, "Temporary Vent Block During Prime CAPA (QIT13-006)," Bates stamped MDT-BRACP-0069836 through MDT-BRACP-0069847, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. You've got that?
A. I do, yes.
Q. This is another PowerPoint slide deck entitled "Temporary Vent Block During Prime CAPA...Project Summary 1/28/2014," about six weeks after the one that you did in December. Correct?
A. Correct.
Q. Is this a PowerPoint slide deck

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that you created?
A. Yes.
Q. All right. And it looks pretty much the same as the one from December. As a matter of fact, it looks exactly the same as the one from December.
Do you know why there was another PowerPoint slide deck that was created six weeks after the other one that didn't really contain any new information?
A. No, I don't remember why.
Q. Do you know what stage the process of developing the new membrane material was at that point?
A. No, I don't remember exactly.
Q. Okay. But you would -- were you in the process at that point of developing the wet flow spec?
A. Again, I can't remember without referring to documentation.
MR. HAVERTY: Can we take a real quick break here?
MR. MERRELL: Sure.
MR. HAVERTY: I'm going to shift

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gears.
THE WITNESS: Okay.
MR. HAVERTY: Thanks.
THE VIDEOGRAPHER: We are now going off the record, and the time is 2:47 p.m.
- - -
(A recess was taken from 2:47 p.m. to 2:58 p.m.)
- - -
THE VIDEOGRAPHER: We are now going back on the record, and the time is 2:58 p.m.
BY MR. HAVERTY:
Q. Mr. Aleksandrovich, if you could look at Exhibit 52, please.
A. 52?
Q. 52, yeah.
- - -
(Deposition Exhibit No. AA-52, Email chain, top one dated February 06, 2014, Bates stamped MDT-BRACP-0050992 through MDT-BRACP-0050994, was marked for identification.)

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- - -
THE WITNESS: 62?
MR. HAVERTY: 52.
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. First of all, who is Mark -- who is Chris Tupper, do you know?
A. Chris Tupper, I'm not sure what his -- what his position exactly was, but he was in the -- I think it was maybe in the risk assessment department, and he communicated with the FDA.
Q. Okay. If you can turn to the second page, all the way at the bottom.
A. Okay.
Q. This is an email from Chris Tupper to Thanh B. Tran at the FDA, and it begins on page 2 there and continues on to the next page where Mr. Tupper says to Mr. Thanh -- or Thanh, I don't know -- "The attached documents includes a description of the current status of our recall of the Paradigm insulin pump, the request for closure document and, the closure request form. The documents will be mailed to the District

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Office via US Postal Service. I addressed the letter to the Recall Coordinator (rather than you personally) so that it will be delivered to whoever is filling in for you in the event you are out of the office."
And then Mr. Tupper goes on to say, "At this point" -- and this is as of December 11, 2013. "At this point, we believe that we have taken all steps within reason to ensure that all affected patients have been notified. In light of this, we are also requesting that FDA consider changing the status of this recall to completed."
Were you aware of the fact that Medtronic made a request of the FDA in December of 2013 to change the status of the recall to complete?
A. Yes, I was.
Q. Okay.
A. Yes, I was.
Q. Did you provide information to anybody that was communicated -- that went into that communication with the FDA requesting that the recall be determined to be completed?

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A. I provided information to Chris Tupper on a regular basis when -- whenever he would ask for -- for it, but I don't know how he used that information in those communications.
Q. Okay. And if you go back to page 1.
A. Yes.
Q. All right. In the middle of the page there, there is an email from Mr. Thanh -- I assume it's Mr., I don't want to be -- make any assumptions, but to Chris Tupper dated January 31, 2014, about six weeks after the initial request. And Mr. Thanh writes, "Hi Chris, the Center For Device and Radiological Health does not concur with the termination of this recall due to:
"1. In Medtronic's CAPA, the firm indicated that it was attempting to find a replacement membrane for the infusion sets. The firm appears to still be in the process of performing this action. The firm has not provided any updated information to verify that a new membrane was acquired, validated, and implemented. Without this information, it cannot

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be confirmed that the firm has adequately mitigated the risk to health caused by this issue."

Do you -- were you aware of that email response or that response from the FDA to Mr. Tupper's request for -- to have the recall deemed complete?

A. Yes, I was.

Q. Okay. And then Mr. Tupper responds about a week later saying, "Hi Thanh, This CAPA is currently in the 'action' phase. Replacement membrane materials have been identified and are being tested, validated and qualified on the product level. The 'action' phase is planned to be completed by March 2015. Upon successful completion of the 'action' phase, a 510(k) submission to FDA may be required prior to the implementation of the replacement membrane material. If no FDA submission is required, the new material will be implemented into production at the end of the 'action' phase; in case a new 510(k) is required, the implementation will immediately follow the FDA clearance (planned for July of 2015)."

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At that point in February of 2014, were you in the process of testing, validating and qualifying a replacement membrane material on the product level at that point?

A. Again, I don't remember exactly at which point of the process we were at that time frame without looking at documents.

Q. Okay. Well, if we go back to Exhibit 2, we note that on page 8, which is the -- it indicates that the validation was expected to take place in May of 2014, and the design review was due in April of 2014. Correct?

A. Correct.

Q. So what was the action phase? The action phase is what? The testing and validation of the product?

A. Among other things.

Q. Okay. What else is included in the action phase?

A. Identification and then testing and validation, procurement, recommendation packages. That's the most involved --

Q. Okay.

A. -- phase of all the CAPA.

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Q. At that point, is it fair to say that you were only focused on Versapor as your material, replacement material?

A. Yes.

Q. If you could look at Exhibit 33, please.

A. 33?

Q. 33, yeah.

- - -

(Deposition Exhibit No. AA-33, PowerPoint, "February CAPA Review FEB 12 Status," Bates stamped MDT-BRACP-0054350 through MDT-BRACP-0054366, was marked for identification.)

- - -

THE WITNESS: Okay.

BY MR. HAVERTY:

Q. This is a PowerPoint slide deck entitled "February CAPA Review February 12 Status, Insulin Delivery by Norma Ojeda."

And we've already established that Ms. Ojeda was your supervisor. Correct?

A. She was at some point. At this point she may have moved on, but I don't

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remember.

Q. And I wanted to ask you that question.

It doesn't really tell you what year this is. It just says "February 12 Status."

Are you able to tell when this would have been referencing?

A. Not without looking at more documentation inside.

Q. Okay all right. Well, if you look at the second page, it has six items on the agenda. Right?

A. Right.

Q. So the first one is "Bergquist," B-E-R-G-Q-U-I-S-T, "on Donatelle."

What's that referring to, do you know?

A. Well, it's a CAPA to replace a part on a pump.

Q. Okay. What pump was it looking to replace?

A. I don't know exactly, but it was a Paradigm pump. I don't know if it was model specific or not.

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Q. Then the next one is the "7xx Phillips."
What is that referring to?
A. Phillips is a supplier that provides cases for the pumps, so -- and 7 refers to the series. So there was some work going on there.
Q. Okay. And then the next one is "5xx Phillips."
Is that related to the 7xx above it, just a different pump size?
A. Yes, yes.
Q. All right. And then the next one is the "A33 Motor Support Phase II."
What is that referring to?
A. That was, if I remember correctly, a redesign for the motor support disc for the motor support cap in the pump housing.
Q. And what was the issue with the motor support cap?
A. It would occasionally become loose and fall out of the pump.
Q. And what was the hazard, if any, related to that?

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A. The hazard was, if I remember correctly, if a patient tries to push it back in, it could initiate an uncontrolled delivery of insulin.
Q. And the next one is the "Prime Fill Anomaly."
So we know that this would have had to have come in the February after the prime/fill anomaly was detected. Correct?
A. Correct.
Q. You just don't know -- you can't tell just looking at it whether it was February of 2014 or February of 2015. Right?
A. I cannot really.
Q. If you go to the page -- and skip over -- and by the way, those -- those six bullet points are referring to different CAPAs that were open. Correct?
A. Correct, yes.
Q. Okay. If you go to the page that's marked last three numbers 364.
A. Okay.
Q. And this is a slide deck -- or slide pertaining to your CAPA for the P-cap

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membrane material replacement project. Right?
A. Correct.
Q. So it looks like as of July of 2013, you had completed the milestone of procuring samples. Correct?
A. Right.
Q. And then it says, the next step was to "Execute initial testing (functional, environment, manufacturing, human, etc.)," as of January 15, 2014. Correct?
A. Correct.
Q. And then if you go all the way over to the "Comments," it indicates as of January 15th of 2014, "All testing completed resulting in 3 materials left for production consideration."
And those were the three materials that we talked about, the PM22S, the Supor and the Versapor. Correct?
A. Correct.
Q. And then the next milestone is "Update documentation (Specifications and Drawings) and procure material for validation." That was -- had a due date of February 10th of

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2014. And at that -- as of this presentation, the status was moved to March 28th of 2014. Right?
A. Correct.
Q. And then it has -- the "Comments" are "Membrane Spec is in Doc Control."
What does that mean?
A. That means -- so there is a document we call materials specification that needed to be updated to create new part numbers for these new three selected membranes, part numbers specific to Medtronic. It's a necessary step in the process like this.
Q. So that it's unique to that particular part number. Correct?
A. Correct. Yes.
Q. And that would -- it would have the part number, and it would have all of the specifications that are associated with that unique part number. Correct?
A. That is correct.
Q. All right. So does that mean that as of March 28th, you expected to have at least the wet flow spec completed at that point

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if you hadn't already?
A. Not necessarily corrected -- connected events. And could have been done internal, but I don't remember exactly the timing again.
Q. Would the wet flow spec have been part of the membrane spec?
A. No, no.
Q. Okay. All right. So what kind of specifications would be part of the membrane spec that was in document control at that point?
A. Okay. So membrane spec intent is to document -- document specifications of unique materials so it can be procured.
Q. Okay. So the dimensions, those types of things. Right?
A. It is basically a drawing for something that's purchased off shelf, that is not made specifically for Medtronic or not customized significantly to Medtronic.
Q. Got it. Okay. Then the next milestone listed is the "Validate 2 materials on CAM 5."
And that has a due date -- had a

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due date of May 14th -- or May 15th of 2014.
And I assume that means since there's no status date, that it was expected to be on schedule?
A. It's -- at this point, it's on schedule, but it hasn't started.
Q. Okay. And what is "CAM 5 will be used for initial validation"? What does that mean?
A. So "CAM" stands for cap acceptably machine. We operate three of them. They're named CAM 3, CAM 4 and CAM 5. At this point of time, CAM 3 and CAM 4 are located at Unomedical's facility in Denmark and are production qualified machines and running production almost 100 percent of the time.
CAM 5 is the newest machine. They're all identical. CAM 5 is the newest machine, and it's housed at our other supplier called TECH Group in Phoenix, Arizona, and it's not qualified for production at that point.
So the decision was to use that machine for validation due to its not being busy with production and proximity to Medtronic.

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Q. Got it.
A. It will make it easier.
Q. Okay. So that was planned to be done sometime in May, be completed as of May of 2014. Correct?
A. At this point in time, this was the plan, yes.
Q. Okay. And then at this point, the next one is "Qualify new material on the product level." And its due date was December 10th of 2014.
That was pushed back substantially from the original date of April 28th of 2015. Correct?
A. Correct.
Q. Do you know why that was pushed back?
A. I don't remember exactly why, but there was a number of factors that caused delays.
Q. Can you remember what some of them were?
A. In documentation processing and procurement process and sometimes testing process, all of those accumulated to the -- to

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the major delay.
Q. Okay. And then the -- at that point, the submission receipt was -- let me go back before I forget.
When we talk about qualifying the new material on the product level, the "Comments" say, "Aging data is being reviewed. Major time contributor."
What does that mean?
A. Our infusion sets marketed by us, made by Unomedical, marketed by us, have a shelf life of three years, basically meaning that unit can be stored for three years while remaining functional and, most importantly, sterile.
Whenever there is a major material change like we're talking about on the product like that, we need to prove that that new material will keep sterile and functional all the way up to the end of the duration of the shelf life, so we need to test it as such. Usually for the reasons of expediency, this testing is performed via so-called accelerated aging, where material is stored at elevated temperature and sometimes pressure and humidity to simulate

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aging.
For example, at the -- at the accelerated rate, one year of aging equals to 50 or 52 days in the environmental chamber. So to simulate -- just to simulate three years' worth of aging test, we needed close to six months of time.
Q. Okay. The next action item is "Submission Receipt." That was expected for August 19th of 2015. And it says it's "Under review. Submission may not be required."
Meaning that you might not have to get the FDA's approval for that?
A. Correct. At this point we are not sure whether it -- we need to submit it to FDA for approval or we can utilize the material without such approval.
Q. What determining factors were there about whether or not it would require FDA approval or not?
A. I can't answer that question. That would be a question for regulatory affairs.
Q. Okay. And then the next action item, milestone, was a "Closing Memo" expected in

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September of 2015.
That would be when you would expect to close out the CAPA?
A. Yes, that's correct.
Q. All right. If you could turn to the next page, please. This has a "P-Cap Update."
And I think you told us that the Versapor that you were working with in 2014 you were focused on was from Pall. Right?
A. Correct.
Q. And this one, on this slide, it talks "About actions due Last Week. Receive material from Porex." And material was shipped on February 24th of '14.
What is it that you were getting from Porex?
A. Material for production validation.
Q. Okay. So it was other than Versapor?
A. Correct.
Q. So were you working on two membrane materials simultaneously?

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A. We were, to reduce the risk of one not passing and then not having to start over.
Q. Okay. What was the other one that you were working on simultaneously?
A. So it was Versapor 450R and the PM22S from Porex.
Q. When did you make the decision to work on both of them simultaneously?
A. I don't remember exactly when.
Q. If you could look at Exhibit A34 -- or Exhibit 34, please.
- - -
(Deposition Exhibit No. AA-34, Engineering Reports, ER14-9258 Version A, 04/25/2014, Bates stamped MDT-BRACP-0054857 through MDT-BRACP-0054865, was marked for identification.)
- - -
THE WITNESS: Uh-huh.
BY MR. HAVERTY:
Q. Okay.
A. Okay.

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Q. And this is an engineering report for P-cap membrane. The design verification testing of P-caps with the Versapor 450R, and it's dated April 25th of 2014.
What is this report about?
A. This report summarizes the results of the testing performed on P-cap assemblies with Versapor 450R material in them manufactured by CAM 5 machine at Tech Group.
Q. Did you have -- did you prepare a similar engineering report around this time for the Porex product?
A. No. Porex was not -- to the best of my knowledge, Porex was not done at the same time yet.
Q. Okay. Do you know why?
A. No, I don't, but you cannot do two materials at the same time. One needs to take natural priority over the other.
Q. Okay. And if you turn to page 8. Okay.
In your "Conclusions," you wrote, "It is a conclusion of this report that Versapor 450R membrane...is a suitable replacement for the

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currently used membrane to be used in production of the PCAP connector assembly. Moreover, the testing captured in this report proved that the ultrasonic welding process developed by the supplier for the Versapor 450R membrane may be used in production.

"Although introduction of insulin to the surface of the membrane reduces the flow characteristics of the material, the membrane remains gas permeable and demonstrated the air flow that is higher than a required minimum of 5 SCCM."

So this engineering testing, was this considered -- was this part of the validation?

A. It's a part of verification, yes.

Q. Okay. So at least as far as your engineering testing in April of 2014, the Versapor 450 was suitable for membrane material. Correct?

A. Correct.

Q. And what was the next step that was planned with the Versapor as of April of 2014?

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A. The next steps were to validate the same -- to -- to repeat the same validation testing for CAM 3 and CAM 4 at Unomedical followed by the production level validation.

Q. Okay. Were you also at that same time anticipating putting the Porex material through the same process?

A. Yes, but not at this time, at a later date.

Q. Were you holding that in reserve in case the Versapor didn't work out?

A. Not only that, it was a constraint -- constraint on the resources and other factors.

Q. Okay. So let me understand this part about it.

Why was it that initially you selected the Versapor as primary over the Porex product?

A. Because it was made by the same manufacturer and same supplier to us, so that relationship was already established and the supplier was qualified. It seemed to -- it seemed promising to fulfill the design

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requirements for us. And that test -- initial testing was successful. And it was commercially -- it commercially made sense as well.

Q. If you could look at Exhibit 35, please.

- - -

(Deposition Exhibit No. AA-35, PowerPoint, "Replacement Membrane for PCAP Assembly CAPA QIR 13-006 Design Review May 9, 2014," Bates stamped MDT-BRACP-0054546 through MDT-BRACP-0054423, was marked for identification.)

- - -

THE WITNESS: Okay.

BY MR. HAVERTY:

Q. This is another PowerPoint slide deck entitled "Replacement Membrane for PCAP Assembly Design Review May 9, 2014."

Do you see that?

A. Yes.

Q. Okay. Was this the design review that you were talking about back in the action

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plan in the CAPA?

A. Yes. Yes, that is correct?

Q. Okay. Did you participate -- did you participate in this design review?

A. I conducted this design review.

Q. Okay. If you look at the second page --

A. Yes.

Q. -- you talk about 5 membranes were initially selected, 3 were chosen for detailed evaluation, and then you note, "1 was selected for production validation based on test results," the "VERSAPOR 450R membrane manufactured by PALL." Right?

A. Correct.

Q. Okay. And you talk -- and the next thing you talk about is the specification for how much fluid may be deposited on the membrane based upon that human factors testing. Correct?

A. Correct.

Q. And then if you go to the next page, you describe all the steps that have been taken up to this point as of May of 2014.

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Correct?
A. Correct.
Q. And if you go to the next page, so you talk about the validation and qualification plan. And you talk about the testing on the CAM 5 machine. Right?
A. Correct.
Q. And then underneath that you have "CAM 3 and CAM 4" at "UNO."
Had this testing been done at Unomedical at this point, or was it anticipated?
A. It's anticipated.
Q. Do you have any idea when it was anticipated to be done?
A. No, I don't remember exactly.
Q. Okay. At this point, as of May of 2014, were you still on target to get the closing memo done by September of 2015, do you know?
A. I don't remember.
Q. But based upon the information that you have, though, as of May of 2014, did it -- does it look like you were on target to close out the CAPA as of September of 2015?

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A. It did.
Q. If you could look at Exhibit 36, please.
- - -
(Deposition Exhibit No. AA-36, Email chain, top one dated July 08, 2014, Bates stamped MDT-BRACP-005460 through MDT-BRACP-005462, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. Okay. This is an email dated July 8, 2014 from you to Hubert Yeung regarding the CAPA status.
Do you see that?
A. Yes.
Q. And you note, "I added a few words about TECH group. I hope this still works."
What was it you were trying to do?
A. I don't remember exactly clarification on what we were doing at Tech.
Q. Okay. So as of July of 2014,

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July of 2014, it was noted that "A new membrane material, Versapor 450R, has been identified." "Uno-Medical and TECH Group are in the process of validating the new membrane on the current production machines."
So do you take from that that Unomedical was in the process of validating the material on the CAM 3 and CAM 4 machines?
MS. MARTINEZ: Objection to form.
THE WITNESS: That is correct.
BY MR. HAVERTY:
Q. And then it goes on, it says, "At the same" -- "at the same time, UNO discovered inconsistencies in the Ultrasonic Welding process and suspended PQs to...work" for -- "further work on Process development."
What is that referring to?
A. That's referring to that during the validation runs -- or actually, PQ run is a mimic of a production run. They discovered some challenges in processing of this material through CAM machines and stopped the validation to go back and look one more time at their processes and try to make it work.

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Q. The PQ refers to product qualification. Correct?
A. Production qualification.
Q. Excuse me. And what was -- what were the inconsistencies that were found?
A. There were voids in the materials and inconsistencies in the welding process that resulted in leakage.
Q. What was the understanding, if there was any, about how these inconsistencies were occurring in the manufacturing process?
A. Can you -- can you ask me again, please? I wasn't clear.
Q. Yeah. We're all getting tired here. Right?
What were the inconsistencies that were -- that were being -- excuse me.
What was hypothesized about why these inconsistencies were occurring? Was it something to do with the manufacturing process? Was it something to do with the material, or was it something to do with both?
A. So at --
MS. MARTINEZ: Object to form.

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THE WITNESS: So at this point, it's both.
BY MR. HAVERTY:
Q. Okay. But you didn't notice these inconsistencies in the validation on the CAM 5 equipment. Correct?
A. That is correct.
Q. So were -- was anybody able to have -- come to an understanding about why the CAM 5 machine could produce the material successfully but the CAM 3 and CAM 4 machines were having difficulty with inconsistent quality or inconsistent results?
MS. MARTINEZ: Object to the form.
THE WITNESS: It was attributed to volume runs. So it was very short runs at CAM 5, and we ran significantly more parts at CAM 3 and CAM 4. And then Unomedical is much more experienced with running these machines than anybody else in the world today. In fact, they possess now all three machines. And they didn't feel comfortable seeing what they

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saw with proceeding to production with this, and they wanted to take it back to reevaluate.
BY MR. HAVERTY:
Q. And was it -- did they deem it was a material issue or was it a -- that it was not suitable for the equipment?
A. It was a combination of, and they tried to modify it by trying different things on the equipment and processing -- process parameters, rather.
Q. Okay. And you said they went back and they were trying some different things.
What kind of different things did they do?
A. They would not disclose. Process parameters with which they run the machines is proprietary information to Uno.
Q. Okay. But they're producing your patented proprietary connector cap to your specifications. Correct?
A. Correct.
Q. So why would they not disclose to you what the issue was with the material that was

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being used to manufacture your proprietary cap?
A. With --
MS. MARTINEZ: Object to the form.
THE WITNESS: With material they disclosed, yes. Material presented some challenges, but process they wouldn't.
BY MR. HAVERTY:
Q. Okay. Do you know that even though they wouldn't disclose it to you, do you know how the processes on the CAM 3 and CAM 4 machines differed from the CAM 5 machine that you were utilizing at Tech Group?
A. No, I don't.
Q. Okay. If you could look at -- strike that.
So when Unomedical decided to go back and look at the different -- relook at it, did the Porex material then come up to the fore for validation?
MS. MARTINEZ: Object to the form.
THE WITNESS: Not at that point, but Porex come up back to validation when

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it was determined by everybody that 450R, Versapor 450R, will be very challenging in a high-volume manufacturing environment.
BY MR. HAVERTY:
Q. So do you know when that decision was made?
A. No. I don't remember exactly.
Q. Well, do you recall whether it was in the summer of 2014 when we note that issue in that email, or was it later, like in the fall, winter?
A. Somewhere in that time frame, somewhere around fall of 2014.
Q. Okay. If you could look at Exhibit 37, please.
- - -
(Deposition Exhibit No. AA-37, Email chain, top one dated July 28, 2014, Bates stamped MDT-BRACP-0051355 through MDT-BRACP-0051357, was marked for identification.)
- - -
BY MR. HAVERTY:

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Q. Do you have that?
A. Yes, I do.
Q. Okay. This is an email chain. The top one on page 1 is from Yu Zhao to, among other people, you dated July 28th of 2014. And in it, it appears to indicate that the FDA has expressed its belief that a 510(k) submission would be necessary for the new material. Correct?
A. Correct.
Q. Okay. So this was at the time when you were sort of revisiting the Versapor material.
Were you looking at the prospect of perhaps going back to the drawing board on these materials?
A. Correct.
Q. Okay. Did you have any type of a timeline in your mind about how long it was going to take to go through this process again to qualify the Porex and get it ready for production development?
A. Yes, I did.
Q. Okay. What was your thinking at

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that time?
A. As far as -- as far as how long is it going to take?
Q. Yes.
A. I don't remember exactly right now, but I would use the same methods and technique that I planned for originally with Versapor 450, because the workload would be the same exactly.
Q. Okay. So it basically took you about a year with the Versapor from the time the material was selected and then shown to be acceptable till you got to the validation testing and the qualification by Unomedical. Correct?
A. A little less than a year, but yes, about nine months.
Q. So were you looking at -- in your mind, was it about the same process, that it would take you another nine months or more to get the new material validated?
A. Yes.
Q. Okay. So you were looking at that point into 2015. Correct?
A. Correct.

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Q. If you could take a look at Exhibit 40, please.
- - -
(Deposition Exhibit No. AA-40, Extension Request Form, 04/13/15, Bates stamped MDT-BRACP-029887 and MDT-BRACP-029888, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. And this is captioned as an "Extension Request Form."
Is this requesting an extension for deadlines in the CAPA?
A. Correct.
Q. And this is indicated that a new due date is requested for 11/13/2015.
And what does that due date require? Is that the estimated date of closing out the CAPA?
A. No. That's just the estimated date to closing of an action phase of the CAPA.
Q. And what's the next step after the action phase? Is it the actual production?

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A. From the CAPA standpoint, it's the collecting data that will be required in order to close the CAPA. It can be different things.
Q. Okay. And you note in the request for extension that "The alternate material qualification has been completed, however due to various constraints and complexity of the testing it was not completed in projected time. Therefore, the FDA submission was not prepared in time that it was originally planned for. The FDA submission will be prepared and executed by UNO Medical. Medtronic will provide all test documentation so it can be included with submission."
So is the FDA submission the date on which you're requesting the extension as the projected date? November --
A. It's a projected date.
Q. Okay. And then you justify it by "The submission preparation requires more time as the testing required consumed more time than originally planned and FDA Submission preparation requires coordination between Medtronic and UNO

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Medical. UNO Medical owns all regulatory submissions on infusion set products."

Was this extension of time necessitated by the fact that the Versapor material didn't work out and you had to go back to the drawing board with the Porex?

A. I don't remember without looking at documentation exactly by this time what had -- what had happened by the time I requested this extension.

Q. Okay. But you knew that sometime in the fall -- summer/fall of 2014, that you were going to have to go with the Porex material at that point. Correct?

A. That's correct.

Q. And you were looking at another nine months, as you said, probably to recomplete the process. So that would have put you sometime into the spring of 2015, correct, when you were making this request?

A. That is correct.

Q. Okay. If you could take a look at Exhibit 41.

- - -

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(Deposition Exhibit No. AA-41, Extension Request Form, 10/26/15, Bates stamped MDT-BRACP-029889 through MDT-BRACP-029891, was marked for identification.)

- - -

BY MR. HAVERTY:

Q. This is another CAPA extension request dated October 26, '15, about six months after the last one we saw. Right?

A. Yes.

Q. Then it goes on to say, the reason for the extension is, "During the execution of the action phase at our supplier (Unomedical), the originally selected replacement membrane material...was found to be difficult to process in large quantities. This resulted in us stopping the material validation activity at Unomedical. Although the membrane material...had already been qualified by the second P-CAP assembly supplier (TECH Group), discussion with both suppliers and our internal team determined that due to manufacturability issues, the" earlier "material would not be suitable for a

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high volume production environment. This resulted in a decision to switch to an alternate membrane material... This change has resulted in a delay in the overall" projected "schedule to complete material qualification activities and implementation."

And it now it looks like the new due date being requested is about six months later, of May of 2016. Correct?

A. Correct.

Q. So this was -- you were in the process then of qualifying the Porex material?

A. That is correct.

Q. And the new due date that was requested, 5/5 of '16, is that the projected submission to the FDA?

A. This is projected completion date.

Q. Okay. In your justification for the extension, you note, "Although the failure that may be caused by a temporarily blocked venting membrane may be critical, the occurrence still remains very low. In addition to the rarity of the potential failure, instructions for

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all Paradigm infusion sets have been updated with warnings and special instructions pertaining to the temporary block issue."

Was it your understanding that those warnings were the ones that we looked at earlier that were in the IFUs?

A. Correct, yes. I am understanding that.

Q. Okay.

"There have been no new observations of the blocked membrane since the instruction update. There are no new product safety risks in extending this CAPA."

Where did you get the information that there were "no new observations of the blocked membrane since the instruction" upgrade -- "update"?

A. I don't remember exactly where, but I would get this information generally from our reporting department.

Q. Okay. And you were aware that as a result of this prime/fill anomaly investigation, that there was a new code that was entered into the system specifically dedicated to

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the blocked vent phenomenon. Correct?
A. Correct. I was.
Q. Okay. If you could take a look at Exhibit 43, please.
- - -
(Deposition Exhibit No. AA-43, Validation Summary Report for CAM 3, Bates stamped MDT-BRACP-029574 through MDT-BRACP-029578, was marked for identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. This is a "Validation Summary Report for CAM 3" with new P-cap material -- P-cap membrane material.
Do you see that?
A. I do.
Q. And there is something that struck me when I saw this report is that was this the validation that was supposed to be done by Unomedical?
A. This is Unomedical, yes.
Q. Yes. Because it's the CAM 3.

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Correct?
A. Correct.
Q. All the way up at the top there, right next to where it says "Validation Summary Report for CAM 3," it has the name ConvaTec and a logo there.
Do you see that?
A. I do.
Q. Who is ConvaTec?
A. As far as I know, ConvaTec is a parent company to Unomedical.
Q. Okay. Had you ever seen materials come by in a -- with a ConvaTec logo before dealing -- in your dealings with Unomedical?
A. I'm sorry. Did I see materials you asked me?
Q. Yeah. Have you ever seen -- have you ever seen that before, that logo on materials that you were dealing with Unomedical on?
A. When you refer to materials, do you mean the product or documentation or both?
Q. Documentation.
A. Yes, I have.

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Q. When did you first start seeing ConvaTec logos on documentation from Unomedical?
A. I don't remember.
Q. In any event, this was the CAM 3 -- is this the production qualification report for the new membrane material?
A. Yes.
Q. Okay. And it's dated December 16th of 2015. Correct?
A. The initial signature, yes. But it wasn't approved until January 4th, I see.
Q. Okay.
A. Completely approved, yes.
Q. Oh, I see what you're talking about there, in the middle there, quality assurance -- "Quality Engineering/Assurance"?
A. Right.
Q. And if you could -- just put that aside and look at Exhibit 44 as well.
- - -
(Deposition Exhibit No. AA-44, Validation Summary Report for CAM 4, Bates stamped MDT-BRACP-029767 through MDT-BRACP-029771, was marked for

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identification.)
- - -
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. Okay. And this is the same validation summary report but for the CAM 4 machine. Correct?
A. That is correct.
Q. Why did you need to do a validation on both the CAM 3 and CAM 4 machines?
A. That's a procedural requirement. Every equipment needs to be -- every piece of equipment needs to be validated separately.
Q. Those machines, though, are identical, are they not?
A. Yes. To the -- for the most part.
Q. Okay. So this was testing that was done then sometime in December of 2015 with the new Porex material. Correct?
A. Correct.
Q. So you had been able to get through all of the testing and the manufacturing issues with the Porex material that you couldn't

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get with the Versapor. Correct?
A. That is true, yes.
Q. So at this point you were getting ready to put it together and submit it to the FDA. Correct?
A. No.
Q. Okay.
A. No, not yet.
Q. What was the next step?
A. This next step would be qualification on the product level and also all the verification testing, including aging testing at Medtronic.
Q. Okay. And how does aging testing take place? How is that done?
A. Sample units are placed -- again, this is as we talked -- as we talked earlier, this is an accelerated aging test. Sample units are placed in the oven at the determined parameters, temperature, usually temperature, sometimes pressure or humidity. And they're kept there for a determined -- predetermined period of time, after which they're pulled out and subjected to functional testing.

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Q. Okay. How long does that typically take for this -- for that material?
A. In this particular case, it took about 50 or 52 days to represent each year of aging.
Q. 52 days?
A. 50 or 52 days.
Q. Okay. Once the aging was completed, would that be the last step before submitting to the FDA?
A. After completion and release of a report summarizing the results of all the testing and providing that report to Unomedical, at that point it was in Unomedical's hands to submit.
Q. Okay. If you could take a look at Exhibit 46, please.
- - -
(Deposition Exhibit No. AA-46, Email chain, top one dated 3/4/2016, Bates stamped MDT-BRACP-029773 and MDT-BRACP-029774, was marked for identification.)
- - -
THE WITNESS: Okay.

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BY MR. HAVERTY:
Q. All right. This is -- the top one is an email from Henrik Nielsen to you, among others, dated March 4th of -- no. I guess, is this April or March 4th, because I know in Europe they do it backwards. They do it differently.
MS. MARTINEZ: Yes.
BY MR. HAVERTY:
Q. Is it --
A. This is March. If you look at the second email, it says 3rd March --
Q. March.
A. -- in Danish.
Q. Got it. So it's March 4th of 2016 indicating that the 510(k) submission were sent to the FDA as of that date. Correct?
A. Correct.
Q. Okay. So at that point everything had been done and it was ready for the FDA's review. Correct?
A. Correct.
Q. Okay. If you could look at Exhibit 47, please.
- - -

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(Deposition Exhibit No. AA-47, Unomedical A/S Medtronic Subcutaneous Infusion Sets with P-Cap Premarket Notification Special 510(k), Bates stamped MDT-BRACP-028752 through MDT-BRACP-028857, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. You got that?
A. I got it.
Q. Okay. And this is a copy of the original initial 510(k) submission to the FDA for the Medtronic subcutaneous infusion sets with P-cap premarket notification special 510(k). Correct?
A. I never seen this document before, but looks like it.
Q. Okay. Would you typically have seen the 510(k) submission?
A. No.
Q. Why not?
A. To be honest, I don't know -- I don' t know how to answer to this question, but

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it's not a part of my responsibility, so I leave it with my regulatory affairs partners to take care of this.
Q. Okay. If you could turn to page 4, page 4.
A. Okay.
Q. And this is a letter addressed to the US Food and Drug Administration on, again, ConvaTec letterhead. Correct?
A. Correct.
Q. Okay.
MS. MARTINEZ: Object to form.
BY MR. HAVERTY:
Q. Okay. Well, would you agree with me, Mr. Aleksandrovich, that at the top right-hand side of the letter is a logo and underneath of it is the name ConvaTec. Correct?
A. Correct.
Q. And it's dated March 1st of 2016. Correct?
A. Correct.
Q. Okay. If you look down at the bottom there, where it says "Reason for Change."
Do you see that?

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A. Yes.
Q. Okay. And this is represented to the FDA, "This submission describes the change in material made to the P-Cap membrane. This change is a part of the corrective action commitments made by Medtronic related to the Class I Field Corrective Action."
Did you -- do you recall that Medtronic made corrective action commitments to the FDA as a part of the Class I recall from June of 2013?
A. Yes. In the letter previously discussed Jeff Hubauer made that commitment to the FDA.
Q. Okay. And then it says "Medtronic communicated to FDA a short term and long term plan of action as part of the recall, where the immediate action taken was addition of a warning to the infusion set IFUs and the longer term action which was to source and implement a replacement membrane that is able to remain gas permeable with certain amount of liquid deposited in the P-cap." Correct?
A. Correct.

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Q. And that was consistent with the entire CAPA process that you followed from 2013 through 2016. Correct?
A. Correct.
Q. All right. If you could turn to page -- the last three numbers are 759.
A. Okay.
Q. And in paragraph 1.9 there, it lists company contacts. And over on the right, one of the contacts is listed as a Lee Leichter, president of P/L Biomedical in Fort Myers, Florida.
Do you know who Mr. Leichter is?
A. I do.
Q. Who is he?
A. He is a person that represents Unomedical or helps Unomedical in the affairs with FDA.
Q. Okay. And what is P/L Biomedical?
A. I'm not sure what P/L Biomedical is.
Q. Is he a consultant, to your knowledge?

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A. Yes, he is a consultant.
Q. Okay. If you could go to page 765.
A. Okay.
Q. Paragraph 5.1. 5.1.1.
A. Okay.
Q. "Change Description. The only change to the device was a change in the material of the P-Cap membrane. The change in the membrane material was a direct outcome of a recall issued by Medtronic June 2013 during which Medtronic committed to the FDA to source a new membrane material to reduce the potential for the membrane to become occluded when wet. The current Membrane material, a Pall Emflon PTFE Membrane that is laminated to non-woven polyester support material, will be replaced with a Porex 100% PTFE material." Right?
A. Right.
Q. Now, what about the Porex? We went back and we talked about when Mr. Grover did the testing where you turned the PTFE layer of the membrane inward and you still couldn't maintain air flow.

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What was different about the Porex material made of PTFE that would still allow air flow, gas permeability?
A. Because Porex is nothing but PTFE. There is no polyester layer, and it doesn't matter which way Porex is attached to the P-cap. It will remain hydrophobic, and it will remain gas permeable.
Q. Okay. But that's what I'm trying to understand is, is that how come if you turn the PTFE layer in on the Emflon material, the PTFE layer still would not be gas permeable if it got wet as Mr. Grover's testing showed?
A. So if Emflon material is inverted, then it will be become gas impermeable when liquid is introduced from the outside of the pump.
Q. From the outside.
But did they -- did you test air flow by introducing liquid on the inside of the cap with the inverted PTFE layer?
A. I don't remember exactly how Ben did this.
Q. Okay. I'm just trying to

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understand, because it seemed to me, the impression that I got was that the purpose for inverting it was to seeing if going with the PTFE layer would be adequate to preserve the gas permeability, and it didn't sound like that worked?
A. Again, I need to look at exactly what Ben did with that experiment.
Q. Okay. And in any event, it indicates what the current material is, is Pall Corporation, it's the Emflon PTFE membrane which was going to be replaced by the Porex porous PTFE materials. Correct?
A. Correct.
Q. Okay. By the way, if you could turn to the page that ends in 805.
A. 805? These are not numbered.
MS. MARTINEZ: Look right here.
- - -
(A discussion off the record occurred.)
- - -
THE WITNESS: Okay.

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BY MR. HAVERTY:
Q. Okay. This looks like the packaging of the infusion sets, does it not? It indicates Med --
A. This is -- this is a back page of an IFU.
Q. Okay. And it indicates at the top there, it has "Medtronic" and then underneath of that it has a logo, it says, "Unomedical, A ConvaTec Company."
Do you see that?
A. I do.
Q. Let's see. We saw that email where you were informed that the 510(k) had been submitted to the FDA in March of 2016.
But you said a copy of that was not sent to you. Correct?
A. I did not say that.
Q. Okay.
A. I was not interested in a copy.
Q. Why were you not interested in a copy?
A. Like I said, I will -- this is a regulatory affairs document, and I don't think I

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have any business in that document. I provided all the information requested, and that's where it stops.
Q. Okay. And is today the first time that you've ever seen this submission?
A. Correct.
Q. Okay. Once the submission was made to the FDA, did you not have any involvement or follow-up on anything after that at all?
A. I did.
Q. What did you do?
A. So the FDA responded with some questions for -- and asked for additional informations -- information on that submission, and that's where I got involved. I helped Unomedical to develop answers to those questions that FDA provided.
Q. If you could look at Exhibit 48, please.
- - -
(Deposition Exhibit No. AA-48, Deficiency List, Bates stamped MDT-BRACP-028858 through MDT-BRACP-028860, was marked for

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identification.)
- - -
THE WITNESS: I got it.
BY MR. HAVERTY:
Q. Is this the FDA deficiency list that you helped Unomedical to respond to?
A. Yes.
Q. Okay. And I love this with the FDA, they never seem to date anything.
A. Never noticed.
Q. Do you know when this deficiency letter was generated?
A. No. I don't remember exactly when.
Q. Okay. All right. Then if you can look at Exhibit 49, please.
- - -
(Deposition Exhibit No. AA-49, Extension Request Form, 04/13/16, Bates stamped MDT-BRACP-029892 and MDT-BRACP-029893, was marked for identification.)
- - -
THE WITNESS: Okay.

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BY MR. HAVERTY:
Q. All right. This is another CAPA extension request dated April 13th of 2016, signed by you. Correct?
A. Correct.
Q. And you note that the reason for the extension was "The special 510(k) submission was prepared by and sent to FDA by Unomedical... however it was rejected by the FDA. FDA requested that the submission be converted to a traditional 510(k) submission. Such submission requires a review period of up to 90 days as opposed to originally planned 30 days for the special 510(k) submission. A resubmission will be required thus further expanding the action phase."
And then you note the justification was because of the FDA's requirement that the special 510(k) be committed -- converted to a traditional 510(k).
Do you know what the reasons were for the FDA requiring that?
A. No, I don't recall.
Q. Okay. If you could look at

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Exhibit 50, please.
Oh, before you do that, looking back at Exhibit 49, so it looks like the new target date for completing the CAPA was November 18th of 2016. Correct?
A. Correct.
Q. Okay. If you could look at Exhibit 50, please.
- - -
(Deposition Exhibit No. AA-50, Porex FDA Questions Response, Bates stamped MDT-BRACP-028861 through MDT-BRACP-028889, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. If you can go through this just real quickly and tell me which responses you assisted Unomedical with, just by number.
A. Yeah. 11, 12 questions, yeah.
No, no. I remember that there was 11 or 12 questions. I helped on some of them.
It's not going to be an easy task

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to do this.
Q. Because they're kind of enmeshed?
A. They're meshed together, and the wording that I provided may have been changed to be more suitable for FDA submission.
Q. Okay. Did you do any additional testing or any type of validation, or is it simply responding with documentation or explanations?
A. It's the latter. Yeah. There was no additional testing required.
Q. Okay.
A. It was mostly clarification work.
Q. Okay. Do you remember how much time you spent on this?
A. Probably back and forth, around two weeks.
Q. And do you know when the -- when this was submitted to the FDA?
A. No, I don't remember.
Q. Were you provided a copy of the submission to the FDA?
A. I don't remember.
Q. If you could take a look at

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Exhibit 51, please.

- - -

(Deposition Exhibit No. AA-51, Letter dated August 10, 2016, Bates stamped MDT-BRACP-028890 and MDT-BRACP-028891, was marked for identification.)

- - -

THE WITNESS: Okay.

BY MR. HAVERTY:

Q. And this is a letter -- the FDA dated this one -- a letter dated August 10, 2016 from the FDA to Unomedical indicating that they reviewed the 510(k) premarket notification and found that the device was substantially equivalent to legally marketed predicate devices marketed in interstate commerce.

So this is basically the date of the approval or the substantial equivalency letter from the FDA. Correct?

A. Correct.

Q. So it was at this point that Unomedical could begin production of the materials contained in the new membrane.

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Correct?

A. No, not exactly, this is not last point. There are a few steps to be taken before that.

Q. Okay. What needed to be done at that point?

A. It's -- it's a documentation release from so-called prototype status to production status.

Q. And what does that involve?

A. In this case, changing drawings mostly and a few bill of -- bills of materials and processing and engineering change order at Medtronic.

Q. Okay. How long would that process ordinarily be expected to take?

A. Normally three, four weeks. I don't remember how long this one -- this exact one took.

Q. Would you have begun that process or at least put it in place in anticipation of getting FDA approval so that you could move on to production as expeditiously as possible?

A. Not back then.

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Q. I take it from your answer, do you do that today?

A. Yes. Due to the -- due to the systemic change that Medtronic has implemented.

Q. When did Medtronic implement this systemic change?

A. In August of 2017, I believe.

Q. Do you know what it was --

A. Or a little earlier.

Q. Do you know what it was that prompted this systemic change?

A. It was just the modern technology. We implemented a paper-free system.

Q. So at the time the FDA approved this, you did not have in place the mechanisms by which you could expedite getting into production. Right?

A. We didn't. Correct.

Q. Okay. So you expected that that could take another month or so?

A. Yeah. Yes.

Q. So we're talking about mid-September at that point?

A. Somewhere -- something to that

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extent.

Q. It would have been at that point that Unomedical would have been in a position to begin production of the membranes, the P-caps?

A. No.

MS. MARTINEZ: Object to the form.

THE WITNESS: No.

BY MR. HAVERTY:

Q. What would have to happen before -- before that?

A. Medtronic providing complete set of production release documentation to Unomedical and I would assume a properly executed purchase orders.

Q. Okay. How long do you think that process would take?

MS. MARTINEZ: Object to the form.

THE WITNESS: Which one? If you can clarify, please.

BY MR. HAVERTY:

Q. Well, we've established that there were certain documentation that would need

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to be done and it would take about a month, so we're into September now of 2016. Then you said there were additional documentation that would have to be done and purchase orders and all that.

How long would you expect that process to take before Unomedical would be in a position to begin manufacturing the new P-caps?

A. Okay.

MS. MARTINEZ: Object to the form.

THE WITNESS: So as far as providing production documentation, that's literally one email from me. I cannot speak to the length that it takes purchase orders to be executed. And then upon that, Unomedical would be -- would be free to procure new material, which has its own lead time. And only then, after receipt of said material, they can start production.

BY MR. HAVERTY:

Q. And again, there were no processes in place to expedite that process once the FDA approval was achieved. Right?

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A. Not --

MS. MARTINEZ: Object to the form.

THE WITNESS: Not to my knowledge.

BY MR. HAVERTY:

Q. So everything was going to be done in the normal, ordinary sort of bureaucratic process that you would do for any other type of procedure. Correct?

MS. MARTINEZ: Object to form.

MR. MERRELL: Objection to form.

THE WITNESS: That is correct.

BY MR. HAVERTY:

Q. Given the hazard of the old material, was there any sense of urgency in getting the new material onto the market?

MR. MERRELL: Objection to form.

MS. MARTINEZ: Object to the form.

THE WITNESS: There was no new urgency introduced at this point after -- after mitigating it with wordings and -- and everything else that we've done.

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BY MR. HAVERTY:

Q. Okay. If you go back to Exhibit 2, please, and look on page 61.

A. I'm sorry, 61?

Q. 61. Yes. I think it's 61.

MS. MARTINEZ: 61?

MR. HAVERTY: 61.

THE WITNESS: Okay. Yes.

BY MR. HAVERTY:

Q. This is from the final CAPA report, and it's under the "Result," it says. And it says, "The Action Phase for this CAPA has been completed as planned."

And by the way, it's dated November 9th of 2016. Correct?

A. Correct.

Q. It says, "The Action Phase for this CAPA has been completed as planned. Upon identifying possible alternative materials that could be suitable for replacement of the currently used PCAP membrane material, those possible alternatives were thoroughly tested. Testing revealed that membrane material manufactured by POREX in a clear choice for

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replacement of the currently used PCAP material. The membrane spec document and PCAP assembly drawing...were up" and -- "were updated with prototype versions of the Membrane material itself...as well as PCAP assembly version featuring new POREX material."

That was basically, you were just describing that the CAPA phase of the project is complete at that point. Correct?

A. Correct.

Q. If you go down to the last -- the last paragraph on that, it says, "Upon successful completion of all testing, the material change was submitted to FDA for review and the approval to implement new membrane material into production was granted. All documentation was updated to production status (...released on 10-10-16)."

Do you see that?

A. I do.

Q. That was -- that's ECO. That's an engineering change order. Correct?

A. Correct.

Q. Is that the last step that's

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necessary for the manufacturer to begin the manufacturing process?
MS. MARTINEZ: Object to the form.
THE WITNESS: Yes. It's a trigger for supplier to start executing.
BY MR. HAVERTY:
Q. Okay. And then it goes on, it says, "and the supplier was notified to phase new material into production as soon as the stock of current material is depleted."
Was that referring to the current stock of Emflon material?
A. That is correct.
Q. So do I -- so it says, "Production is scheduled to start January of 2017." Correct?
A. Right.
Q. So it was anticipated that from at least October, if not from earlier than that, until January of 2017, Unomedical was going to continue to manufacture infusion sets with the connector cap with the Emflon membrane still in it. Correct?

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A. Correct.
Q. And that was in order to deplete the supply that was already remaining before beginning the production with the new material. Correct?
A. Correct.
Q. Who made that decision, that you should deplete the current stock of material before beginning production with the new material?
A. Medtronic.
Q. Who at Medtronic made that decision?
A. I don't remember exactly who held that discussion.
Q. Okay. Were you a part of it?
A. At some point or the other, yes. At least I presented this to -- to my management.
Q. Okay. Did you concur in the conclusion that you should deplete -- that Unomedical should deplete the Emflon material before beginning production with the new Porex material?
A. Yes, I did.

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Q. Okay. Did anybody express any dissent with that, that they should get the Porex material into production as soon as possible?
A. No, not that I remember.
Q. Okay. And in fact, correct me if I'm wrong, but the infusion sets containing the new Porex material didn't actually come to market until about April of 2017. Correct?
A. That is correct.
Q. When did production of those sets actually begin?
A. I cannot answer that question, because that is internal Unomedical scheduling.
Q. Okay. So you have no idea when it happened. Right?
A. That is correct.
Q. But it had to have happened sometime before April 2017. Correct?
A. Yes.
Q. Did you have any sense of how long the lead time was between Unomedical beginning production of the new infusion sets and them getting them over to Medtronic to put them out onto the market?

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A. Yes, I did.
Q. What was the lead time?
A. So I just want to clarify. It's not the beginning of production of the infusion sets. It's the beginning of production of P-cap assemblies.
Q. Right. What I'm trying to understand is --
A. Which is a -- which is a step -- which is a step previous to the -- to the manufacturing of the infusion set. The regular lead time for something like this is around four months.
Q. You mean -- what I'm trying to understand is, is that Unomedical was expected to begin producing the new P-caps with the membrane in January of 2017. Correct?
A. Correct.
Q. And then you think the -- between the manufacturing of the P-caps and the assembly of the completed infusion set and return to Medtronic, you think the lead time would be about four months; is that correct?
A. That is correct.

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Q. So that would indicate, if we were working backward, that if the materials came to market in April of 2017, that that would mean that Unomedical began production of the P-caps in January of 2017. Correct?
A. Around January of 2017.
Q. Okay. And you were aware that it was in September of 2017 that it's a little more than a year after the FDA approved the new material that Medtronic issued a recall for the infusion sets containing the Emflon material. Correct?
A. Correct.
Q. Did you know that that recall was coming?
A. No.
Q. Do you know why the recall wasn't issued in 20 -- in April of 2017 when the new infusion sets became available and on the market?
A. No, I don't. I was not involved in that project.
MR. HAVERTY: Okay. Let's go off the record for a second. I just want to pull one thing up, and we're going to

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wrap this up.
THE VIDEOGRAPHER: We are now going off the record, and the time is 4:16 p.m.
- - -
(A recess was taken from 4:16 p.m. to 7:24 p.m.)
- - -
THE VIDEOGRAPHER: We are now going back on the record, and the time is 4:24 p.m.
BY MR. HAVERTY:
Q. Mr. Aleksandrovich, just a couple of things, and hopefully I'm going to wrap this up very quickly.
You saw a little bit earlier when we were talking about the original recall with the "dear healthcare provider" letter back in June of 2013, and they indicated that the installed base of users was about 428,000 people.
Do you remember that?
A. I do.
Q. Okay. And you're aware of the fact because you run the disposables, the

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consumables portion for Medtronic that these infusion sets are set to be changed about every three days. Correct?
A. That's correct.
Q. Okay. So that means that, if I do the math correctly, a user would make about 121 infusion set changes in a year. Right? Every three days, divided by 365, so that would be 121 infusion set changes. Correct?
A. That's a good approximation, yeah.
Q. So that would -- right. So that would be 121 infusion set changes times 428,000 users. Right?
A. Right.
Q. That would mean in a given year, there would be about just under 52,000 infusion sets sold. Correct?
A. 52 million.
Q. Excuse me. 52 million.
MS. MARTINEZ: Million.
THE WITNESS: Million. The actual number is closer to 65 --

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BY MR. HAVERTY:
Q. Okay.
A. -- million units sold.
Q. Okay.
A. Yeah.
Q. Okay. So it's 65 million units sold.
And it took approximately four years from the time the temporary vent block phenomenon was discovered until the new membrane material went on the market for users. Correct?
A. That is correct.
Q. So if there is 65 million infusion set changes a year and over four years, that would mean that there were 260 million infusion sets sold over that four-year period that had that Emflon material in it. Correct?
A. Correct.
Q. And part of Medtronic's rationale for its proprietary connector in its pump is so that they could exclude other generic companies from marketing infusion sets and reservoirs that could be used with Medtronic pumps. Correct?
MR. MERRELL: Objection to form.

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THE WITNESS: I cannot comment as to the commercial strategy of Medtronic as a company.
BY MR. HAVERTY:
Q. But we know they are looking at 65 million units a year of these infusion sets. Correct?
A. Yes.
Q. Okay. Real quickly, if you could take a look at Exhibit 53, please.
- - -
(Deposition Exhibit No. AA-53, PowerPoint Slides, Bates stamped MDT-BRACP-0081696 through MDT-BRACP-0081716, was marked for identification.)
- - -
BY MR. HAVERTY:
Q. Okay. Have you seen this chart before, by the way?
A. Yes.
Q. Okay. When was the first time you saw this?
A. A couple of days ago.

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Q. Okay. And did you understand this to be an analysis of complaints and returns related to the possible temp vent blockage complaints that were now coded GA50?
A. Yes. But I wouldn't call it an analysis. It's just a pure data collection.
Q. They were just raw numbers. Correct?
A. Correct.
Q. But in any event, these -- all these pages that go, beginning in June of 2013 and they continue on reporting both complaints and returns coded under the GA50 possible temp vent blockage complaints through May of 2014. Correct?
A. Correct.
Q. It's about a year. Right?
A. Right.
Q. So if you look at June of 2013, it looks like there are about 110 complaints coded under the GA50 complaint code?
A. Correct.
Q. And then in July it looks like there are about 85, 83 to 85 complaints?

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A. Yes.
Q. Okay. And if we keep going on, each page adds another month. So in August of 2013, there are about 85 complaints under GA50. Correct?
A. Correct.
Q. And then the next one is September of 2013. It looks like it's about 62 complaints recorded?
A. Correct.
Q. And then October of 2013, it looks like 59, just under 60?
A. Right.
Q. Okay. And by the way, just so we're clear, this GA50 complaint code starts right at the time where Medtronic had issued the "dear healthcare provider" letter and the "dear patient" letter warning about the getting insulin on the reservoirs. Correct?
A. Correct. When that code was specifically created for this.
Q. Right. So all of the data is following that warning. Correct?
A. Correct.

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Q. So now in November of 2013, we've got recorded as 60 complaints. Correct?
A. Correct.
Q. And then December it's about 61. Right?
A. Yes.
Q. And then in January, it looks about 42, 43?
A. Right.
Q. And then in February, it's 40?
A. That's right.
Q. March, it's 41?
A. Correct.
Q. And then in April, it's 40 -- about 45?
A. Yeah, about that.
Q. Okay. And then in May, it is about 58 or so?
A. Correct.
Q. Now, I went and I added all those up, and the number that I got was that in the 11-month period between June of 2013 and May of 2014, there were 750 complaints that were coded under the GA50 possible temp vent blockage code.

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Does that seem -- does that seem fair?
A. It does.
Q. Okay. So that would be contrary to what you put in that note, that in your extension request for the CAPA, that there were no new reports of this phenomenon at the time. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: Okay.
BY MR. HAVERTY:
Q. Is that fair?
A. It's fair --
Q. We know that --
A. We didn't know that -- I meant that there were no hospitalization or some serious complications recorded.
Q. Okay. But we know that at a minimum, there were about 750 complaints that were coded under GA50?
A. Again, according to this -- to this chart, without doing any analysis, yes.
Q. Right. But putting aside whether there were hospitalizations or any injuries, per

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se, would the fact that there are 750 complaints about this phenomenon of the insulin coming out on its own indicate that the problem you were -- that you had initially anticipated was still there, that patients were getting insulin on the reservoir caps and somehow contaminating the connector caps. Correct?
A. Again, I cannot make that assumption or conclusion judging from this data without looking at actual complaints.
Q. But the GA50 code was specifically created to capture those types of complaints. Correct?
A. That is correct.
Q. Okay. So would you infer from that that regardless of whether there are hospitalizations or injuries, that the underlying problem which the membrane redesign was intended to correct was still there and some patients were still doing the incorrect filling procedure, regardless of whether they were injured or not?
A. Again --
MR. MERRELL: Object -- objection to the form.

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THE WITNESS: Again, I cannot conclude or make that statement based on what I'm -- what I'm looking at, without going into further details on the analysis.
BY MR. HAVERTY:
Q. Okay. And that would be part of the quality improvement team, I guess, would it not?
A. That is correct. And speaking of that, just to add to that, we -- quality improvement team works in -- in percentages, and signal needs to make it to a certain percentage of failures as compared to units sold before it becomes a real issue.
So if you look at the -- at the right side of the chart, we're talking about .001 -- between .001 and .00 -- at maximum 3 percent of units sold at 65 units -- at 65 million units a year.
Q. Right. And that -- I'm sure that Medtronic thought that that was a very comforting number.
However, if you're looking at 110

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complaints of this temporary vent blockage in June of 2013, after the warnings had come out, any one of those 110 could have resulted in an injury or death. Right?
MR. MERRELL: Objection to form.
THE WITNESS: Can't -- can't make that assumption, because I don't know what was reported and what the patient saw and how the report was taken and what would be the result of the analysis of that particular infusion set.
BY MR. HAVERTY:
Q. But all I'm saying is, is that if a temporary vent blockage occurs, Medtronic was aware that that could lead to the over-infusion or under-infusion of insulin. Correct?
MR. MERRELL: Object to the form.
THE WITNESS: That is correct.
BY MR. HAVERTY:
Q. Okay. And that was the entire purpose of redesigning the membrane material so that you wouldn't get 110 complaints or 60 complaints in a month of this temporary vent blockage phenomenon. You were going to eliminate

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that phenomenon. Correct?
MR. MERRELL: Objection.
BY MR. HAVERTY:
Q. Or at least reduce it to the lowest possible.
A. That we would eliminate that phenomenon, but that doesn't mean that we will stop receiving complaints.
Q. What else could cause a temporary vent blockage phenomenon other than --
A. Again -- so a person -- and I don't want to say anything bad about people, but I need to see -- me personally, I need to see the report exactly to understand whether it's a valid report or it's a misunderstanding of the issue or if it's a misrecording of an issue, a misclassification on the issue on the Medtronic side. That's possible as well.
So again, that chart that we just discussed, it's completely inconclusive to me as part of the real failure and the real issue at hand.
Q. And just -- and this probably will be my last question.

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Are you aware one way or the another of whether the help line employees were trained on utilizing this new GA50 code for the precise purpose of trending what this phenomenon was -- how it was occurring out in actual use?
A. I'm sure there were trained to some extent. I don't know exactly the extent of the training and the detail of the training. Again, that is out of realm of my responsibility, and I cannot answer for that department.
MR. HAVERTY: Right. Mr. Aleksandrovich, I don't have anything further for you. Thank you.
THE WITNESS: Thank you.
MR. MERRELL: I have a few questions. I assume Marlene doesn't have any questions?
MS. GOLDENBERG: Not for now, no.
MR. MERRELL: Okay.
THE WITNESS: Are we going to refer to any of this?
MR. MERRELL: We may. If it's not organized, you can use my copy.
THE WITNESS: Sorry.

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MR. MERRELL: I know. Because it may be hard to find it. Just a few questions.
- - -
EXAMINATION
- - -
BY MR. MERRELL:
Q. When did you begin your involvement with the temporary vent block CAPA again?
A. Around summer -- spring/summer of 2013. I don't remember exactly when.
Q. And how many years ago was that from today?
A. Five already.
Q. Do you recall all of the details from the CAPA sitting here today four, five years later?
A. No. I can't possibly remember everything.
Q. Okay. Was the temporary -- was the temporary vent blockage issue a result of a design problem?
A. No, it was not.

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Q. Were --
A. Or it is not.
Q. Was the temporary vent block issue a result of a design flaw with the -- with the infusion set?
A. No, it's not.
MR. HAVERTY: Objection.
Are you -- Cliff, are you producing him as an expert witness?
MR. MERRELL: I haven't decided yet, but I'm just simply asking the questions as it stands now.
What ws --
MR. HAVERTY: Well, I think -- cliff, let me note my objection.
If you intend to qualify him as an expert witness, then I'm entitled to a report.
MR. MERRELL: Okay. I understand your position.
BY MR. MERRELL:
Q. What was the temporary vent block issue a result of?
A. An incorrect filling process of

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reservoir, which is basically advertently or not advertently not following the instruction.
Q. And has that been documented in the various documents we looked through today from the CAPA?
A. Yes, it was.
Q. And as a result of the improper reservoir filling, did Medtronic and did you, were you looking for a potential design solution to address this user error?
A. Yes.
Q. And you testified earlier that -- about the instructions and the warnings alone were not a good enough solution for you with respect to the CAPA.
Can you explain that?
A. Right. Not necessarily. I may have used the wrong term. Not that they're not good enough, but we wanted to follow through and create something even more robust that will not only prevent but eliminate the potential of failure.
Q. And why is that?
A. Because as a company, Medtronic,

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our patients are of the utmost concern to us, and we make them as safe as possible.
Q. And there's a testimony earlier, questions earlier about CAPA and there being a corrective and then preventative component of it.
Do you recall that?
A. I do.
Q. Do you compartmentalize the various actions taken in the CAPA between a corrective versus preventative action?
A. No, I don't.
Q. Can you explain that?
A. A CAPA is merely a name of a process that's intended to improve upon something, and any actions taken in there are all towards the success, but that's ultimately success of the project. And I wouldn't categorize them one are -- some are more important, some are less, some are corrective, some are preventative. It's all -- it's all leading to.
Q. So for example, with the warnings, the notification, would you categorize those just in a specific bucket of corrective or

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preventative?
A. No, I wouldn't.
Q. And with respect to the material change in the membrane, would you characterize that as a corrective or preventative measure?
A. No, I wouldn't. They all have the ultimate goal, the same ultimate goal.
Q. You testified that it took I guess between three-and-a-half and four years to change the membrane material; is that correct?
A. That's correct.
Q. Did you have any concerns that it took three-and-a-half years to four years to change the membrane?
A. No.
Q. And can you explain that?
A. Yes. Because the warnings that we issued and the steps that we took with those warnings to our understanding and best knowledge were significant enough and robust enough to carry us through the design change.
Q. And did you believe that those efforts were sufficient to carry through the design change?

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A. Yes, we did.
Q. Can you explain why did it take three-and-a-half years to make the membrane change from the beginning of the CAPA?
A. It's due to multiple reasons. So first, obviously, we had material. We selected material that looked good at the beginning and fulfilled the design requirements at the beginning but proved to be not very usable in a high volume manufacturing. Also, since we are in the very regulated industry, we have to follow certain step and take certain -- certain precautions and certain documentation steps and sequences, sometimes directed by government that just cannot simply do -- get done faster than they can.
Q. Can you take a look at Exhibit 2 on page 8 again.
A. Yes.
Q. And if you look on page 8 through 9, are there 16 various action steps and phases that are listed here?
A. Yes, there are 16.
Q. And can you explain, are these

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required for you to be able to make this decision change for the P-cap?
A. Yes, they are.
Q. And why is that?
A. Again, because we need to adhere to certain procedures and certain rules and regulations and also need to do a fair amount of testing and other activities that are involved.
Q. In replacing the material membrane for the P-cap, is there a risk or concern that the solution could actually cause more problems than the original membrane?
MR. HAVERTY: Objection.
THE WITNESS: No, there is not. There is no such concern.
BY MR. MERRELL:
Q. And why is that?
A. Because we proved by it testing and verification that there is not.
Q. To be able to eliminate that concern, did you have to go through these processes?
A. Yes, we did.
Q. And are these processes part of

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the quality system at Medtronic?
A. That is correct.
Q. Is that quality system required by FDA regulations?
A. Among other things.
Q. You were asked earlier about Lot 8.
Was Lot 8 and then the temporary vent block CAPA you worked on, was it the same failure mode?
A. They were the same failure -- they produced the same failure mode, yes.
Q. Was it the same failure mechanism?
A. Not at all.
Q. Can you explain that?
A. Yes. Lot 8 failure mechanism was connected to a manufacturing process utilized back at that time with the production of silicone oil for lubrication of the inside of the P-cap. And once that oil was removed, the problem went away; whereas temporary vent block failure mechanism has to do with accidental introduction of any fluid onto the P-cap membrane.

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Q. And in the Lot 8 CAPA, did that address the failure mechanism there?
A. For the -- identified for Lot 8?
Q. Yes.
A. Yes, it did.
Q. Was the temporary vent blockage CAPA that you worked on, was that an important project for Medtronic?
A. It was.
Q. Did Medtronic expend a significant amount of resources on that CAPA?
A. Every required resource was at my disposal.
Q. Why is that?
A. Because it was important to patient safety ultimately.
Q. Has the FDA ever been critical at all regarding the amount of time it took to implement the membrane material change under the CAPA?
A. Not that I'm aware of.
Q. You discussed different materials that were evaluated for changing the membrane for the P-cap.

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What was the original choice for Medtronic?
A. The original was a Versapor 450R material manufactured by Pall Corporation.
Q. And why ultimately did you have to switch to a different choice?
A. Because despite the fact that it produced acceptable results on the functional side, it demonstrated prohibitive -- prohibitive behavior to be used in the high volume manufacturing environment.
Q. And would that -- does that indicate that there could have been quality issues if you tried to manufacture it?
A. Yes.
Q. You -- as I understand, did you identify three -- ultimately three potential materials that were tested?
A. That is correct.
Q. And how would you characterize the wet flow of those three potential options?
A. As acceptable.
Q. And was there a specification you were looking at and measuring them against?

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A. I don't remember what came first, the wet flow spec or the material themselves that were tried.
Q. Okay. But did you find that those three materials, that they met the requirements for Medtronic?
A. Yes, absolutely.
Q. You were asked earlier about the continuation of manufacturing the membrane using -- utilizing the Emflon membrane.
Do you recall that?
A. Yes.
Q. And as I understand it, the manufacturer utilizing the newer membrane, that began in January of 2017?
A. Correct.
Q. Did you testify you were involved in that decision?
A. I was not involved in that decision. I provided information.
Q. But you testified that you concurred with that decision?
A. Correct.
Q. Why is that?

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A. Because it was safe enough to deplete the material given the precautions --
(Court reporter clarification.)
BY MR. MERRELL:
Q. Why did you concur with that -- why did you concur with that decision?
A. Because it felt -- it felt safe to continue depleting and using the Emflon material due to the steps that we as a company took to prevent the potential failure in the field with warnings and IFUs and such.
Q. You were asked just a few questions at the end regarding Exhibit 53.
Do you recall that?
A. I do.
Q. And there is a -- there's a list of numerically the number of GA50 complaints at the end.
Do you see that?
A. I do.
Q. How would you characterize the rate of those complaints?
A. As extremely low.
Q. What was the range of the rates?

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A. Percentage-wise?
Q. Yes.
A. Less than half -- than significantly less than half a percent.
Q. Without the benefit of the individual complaints, are you able to draw any conclusions based on this data?
A. No, I cannot.
MR. MERRELL: Those are all the questions I have.
MS. MARTINEZ: I have one question.
- - -
EXAMINATION
- - -
BY MS. MARTINEZ:
Q. Mr. Aleksandrovich, you were asked about certain things that Unomedical did in connection with Medtronic's decision to change the membrane to a Porex membrane.
Did Unomedical act with the due diligence that you expected and do everything that Unomedical was asked?
A. Absolutely.

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MR. HAVERTY: Objection, objection.
MS. MARTINEZ: Thank you.
MR. HAVERTY: Note my objection. You're asking him expert witness -- do you want him to produce a report, Ileana? I move to strike that as an expert --
MS. MARTINEZ: Again, this is --
MR. HAVERTY: I move --
BY MS. MARTINEZ:
Q. Just for the record, let me repeat again, you dealt with Unomedical and asked Unomedical to do certain things in connection with Medtronic's decision to change the current membrane or the then-existing membrane to a Porex membrane.
I'm asking you as an employee of Medtronic that dealt with Unomedical, did Unomedical exhibit due diligence in its actions and do everything that you asked --
MR. HAVERTY: Objection.
MR. MERRELL: -- Unomedical to do?
THE WITNESS: Yes, they did.

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MR. HAVERTY: Objection. Again, I move to strike. That's an expert witness question.
Ileana, if you want to ask him -- by the way, Marlene, if you want to jump in on this.
If you want to ask him whether or not they did everything he expected them to do, then that's a different question, but you just asked him a standard of care question.
MS. MARTINEZ: I didn't. No, no. I did ask him what --
MR. HAVERTY: Exercising --
MS. MARTINEZ: -- if they did everything that he expected them to do.
THE WITNESS: Yes, they did.
MR. HAVERTY: No. You asked whether they acted with due diligence. Ileana, you asked --
MS. GOLDENBERG: And Ileana, I'll just note that Kevin has been objecting on behalf of both of us, even though technically you're only appearing in the

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Eklund case, so that objection applies to both.
BY MS. MARTINEZ:
Q. Let me ask it again, just so the record is clear.
In your dealings with Unomedical in connection with Medtronic's decision to change the then-existing membrane in the P-cap to a Porex membrane, did Unomedical do everything that you asked?
A. Yes, they did.
Q. Did they do it in the time frame that you asked them to do it?
A. For the most part they did.
MS. MARTINEZ: Okay. Thank you.
MR. HAVERTY: I just have a couple follow-ups, Mr. Aleksandrovich.
- - -
EXAMINATION
- - -
BY MR. HAVERTY:
Q. You said that you believe that the warnings that were put in place after the temporary vent block process was found were --

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you believe they were robust, and they were -- they were substantial enough to prevent the problem. Correct?
A. Correct.
Q. And as we saw from that email from the FDA, the FDA did not concur with that assessment, did they?
MR. MERRELL: Objection to form.
THE WITNESS: Okay. I'll agree to that.
BY MR. HAVERTY:
Q. And you want to talk about -- you talked about the distinction between the failure mode and the failure mechanism between the Lot 8 and the temporary vent block.
In fact, the mechanism of failure is exactly the same. It's the blocking of the vents, is it not?
MR. MERRELL: Objection to form.
THE WITNESS: That's what you're referring -- in this case, in our industry, judging -- going from the rules how we do the failure mode and effect analysis, that's the failure effect.

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Blocked membrane is a failure effect.
BY MR. HAVERTY:
Q. Isn't the failure effect the over-infusion or under-infusion of insulin? That's the failure effect. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: On the system level, maybe. But if we're talking only about the P-cap, it's the blocked membrane.
BY MR. HAVERTY:
Q. Right. And that's the mechanism by which the failure effect can occur, is the membrane gets blocked, and that can cause an over-infusion or under-infusion of insulin, whether it's from excess silicone oil or from insulin. Correct?
A. Okay. Yes.
Q. The only real difference between the two is one was an identifiable manufacturing defect while the other one deals with a vulnerability in the design of the membrane in the connector cap, the venting membrane. Correct?

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MR. MERRELL: Objection to form.
THE WITNESS: No, I don't agree with that. One was the identifiable manufacturing process issue. The other one is -- we can call it a human factor issue.
BY MR. HAVERTY:
Q. Right. But my point is --
A. But it's not -- it's not a design issue.
Q. Well, it is a design issue because that's exactly what you did in this CAPA, was you redesigned that membrane material to prevent this hazard. Correct?
A. We redesigned to -- to provide a mistake-proof, if you will, ability for users.
Q. Right. Because you know that humans can make mistakes. And so the hierarchy of risk mitigation is to design out a hazard if you can. Correct?
A. That is correct. But the hazard occurred in this case due to the human factor interaction only.
Q. Right. But if the membrane could

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remain gas permeable, the human factors aspect of it wouldn't have mattered. So it was a design issue, was it not?
A. No, it was not.
Q. Okay. So why did you undertake to --
A. It's not considered a design issue.
Q. Okay. But you will agree with me that what you did in the CAPA was you redesigned the membrane. Correct?
A. Yes, yes. I agree with that.
Q. Okay. And therefore, what you did was you proved that it was feasible to design out this hazard of the over-infusion or under-infusion of insulin due to vent block, the blocked vents. Correct?
MR. MERRELL: Objection to form.
THE WITNESS: Not very clear on the question.
BY MR. HAVERTY:
Q. By virtue of the fact that you were able to achieve a redesign, put it into manufacturing and put it out on the market, you

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proved that it was feasible to have a membrane that could remain gas permeable, even if contacted by fluid. Correct?
A. Potentially, yes.
Q. Well, that's what you represented --
MS. MARTINEZ: Kevin we're getting a --
MR. HAVERTY: Okay. I just have one quick question.
BY MR. HAVERTY:
Q. You believe that your mitigation prior to the putting the redesigned membrane on the market was good enough.
Would you agree with me then that if someone suffered an injury from an over-infusion of insulin that could be traced back to a blocked vent situation, that that would prove that your system of risk mitigation was not adequate?
MR. MERRELL: Objection to form.
THE WITNESS: It's -- it's speculation, so we have -- we have proof -- we have proof statistical that

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it hasn't occurred.
BY MR. HAVERTY:
Q. Well, what you have are complaints that are received by Medtronic. If someone was injured by this and didn't report it to Medtronic, you wouldn't know about it. Correct?
A. That is correct.
MR. HAVERTY: That's all I have. Thank you.
THE WITNESS: Thank you.
MS. GOLDENBERG: I just have a few questions, if you don't mind. Sorry. I'll keep it close. I know you guys are getting a signal from the videographer.
- - -
EXAMINATION
- - -
BY MS. GOLDENBERG:
Q. Mr. Aleksandrovich, my name is Marlene Goldenberg. We haven't had a chance to formally meet yet, but I'm here on behalf of the plaintiffs in this case also.
And I believe that you testified

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that safety is the most important thing at Medtronic; is that right?
A. That is correct.
Q. And that's more important than profits. Right?
A. Of course, yes.
(Court reporter clarification.)
MS. GOLDENBERG: My question was that safety is more important than profits, and he agreed.
BY MS. GOLDENBERG:
Q. Mr. Aleksandrovich, I apologize, we need a verbal answer.
A. Yes, it is, of course.
Q. Okay. And in putting patient safety first, that means complying with all regulatory requirements. Right?
A. Right.
Q. But even beyond that, it means that, you know, you don't have to wait for the FDA to catch a problem, that Medtronic should be proactive when they're aware that something is wrong that could compromise patient safety. Right?

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MR. MERRELL: Objection to form.
THE WITNESS: Absolutely.
BY MS. GOLDENBERG:
Q. Okay. And you also testified that the number of complaints that had been reported after the 2013 warning letter went out to patients was an acceptable level; is that right?
MR. MERRELL: Objection, form.
THE WITNESS: Yeah. Acceptable to the method that we measured them with, yes.
BY MS. GOLDENBERG:
Q. Okay. And what is the threshold of how many severe injuries or death is acceptable to Medtronic?
MR. MERRELL: Objection to form.
THE WITNESS: So we're not talking about severe injuries. None of these resulted in severe injuries. It would have been treated completely different. And to answer your question, I am not sure what a threshold for certain failures, but again, severe

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injury is not a regular complaint.
BY MR. HAVERTY:
Q. These 700 -- these roughly 700 complaints that came in were all specific to the new code that had been created after the letter went out to patients. Right?
A. They were recorded under that code, yes.
Q. Okay. And in order to be recorded under that code, health line representatives had to have been trained to recognize that that was the effect that was occurring. Right?
A. Right.
MR. MERRELL: Objection to form.
THE WITNESS: Probably.
BY MR. HAVERTY:
Q. Okay. And if those complaints are still recorded in the reports that we were referring to earlier, those complaints presumably had been validated by someone working at the help line or one of their supervisors. Right?
A. Presumably, yes.
Q. Okay. And Medtronic indicated in

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its dear patient and "dear doctor" letters that the most likely effect of the over-delivery or under-delivery of insulin was hyper- or hypoglycemia. Right?
A. Correct.
Q. And you testified earlier that nothing good can come from an over-delivery of insulin. Right?
A. I'm sorry, I wasn't -- you broke up a little bit.
Q. I believe you testified earlier that nothing good can come from an over-delivery of insulin; is that right?
A. I can hear nothing good can come? Yes. I said that. Of course, yes.
Q. I'm sorry.
Okay. And so I guess what I'm wondering is how is Medtronic making -- strike that.
What is Medtronic's definition of a serious injury?
A. I don't know. I can't answer that question.
Q. Okay. But suffice it to say,

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your position is that these roughly 700 cases were not classified to be serious despite the fact that nothing good can come from an over-delivery of insulin?
A. To what I know at this point without looking at each report individually, yes.
Q. Okay. Switching topics a little bit, you had testified that at one point, Medtronic manufactured a reservoir that would go with a Luer Lock infusion set that was not made by Medtronic; is that right?
A. That's not what I said. I said Medtronic manufactured a reservoir with a Luer Lock interconnection, but the intent of course is to use it with the infusion sets manufactured by Unomedical and marketed by Medtronic with Luer Lock connection as well.
Q. Okay. Could a different infusion set have been used with that reservoir?
A. Yes.
Q. Okay. And was that type of reservoir available in 2014?
A. I believe so.
Q. Was it available in 2016?

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A. I am not sure when we stopped manufacturing that reservoir.
Q. While the new P-cap was being designed, was there ever any thought given to advising patients to use different infusion sets?
A. I cannot answer to that question, but it is impossible to use a different infusion set with a Paradigm pump or NGP pump.
Q. Okay. So let me just make sure I understand, because I may be misconstruing what you're saying.
The reservoir that works with the Luer Lock, that would allow other infusion sets not being manufactured by Medtronic to be used with that reservoir. Right?
A. Correct.
Q. And that combination products could have been used with the Paradigm pump?
A. No, it could not have.
Q. Okay. I understand.
You testified that you didn't really have much to do with the FDA or regulatory issues. Right?
A. Correct.

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Q. Okay. So you're not holding yourself out to be an expert in warnings?
A. Not at all.
MS. GOLDENBERG: Okay. Those are all the questions I have. Thank you for your time.
THE WITNESS: Thank you. Thank you very much.
MR. HAVERTY: I guess we're getting the bum's rush.
THE VIDEOGRAPHER: That concludes -- okay? This concludes the video deposition of Anatoly Aleksandrovich consisting of four DVDs. We are now going off the record, and the time is 5:00 p.m.
(Deposition adjourned at approximately 5:00 p.m.)

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CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, ANATOLY ALEKSANDROVICH, have the opportunity to read and sign the deposition transcript.

ANN MARIE MITCHELL, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Registered Merit Reporter and Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 340, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
ANATOLY ALEKSANDROVICH DATE

Subscribed and sworn to before me this _____ day of _____, 20____.
My commission expires:_____

_____
Notary Public